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OFFICE OF MANAGEMENT AND BUDGET

2 CFR Part 200

Uniform Administrative Requirements, Cost Principles, and Audit Requirements

AGENCY: Office of Management and Budget (OMB).

ACTION: Guidance.

SUMMARY: This document announces the availability of the 2021 Compliance Supplement (2021 Supplement) for the Office of Management and Budget's uniform administrative requirements, cost principles, and audit requirements regulations. This document also offers interested parties an opportunity to comment on the 2021 Supplement.

DATES: The 2021 Supplement replaces the 2020 Supplement (issued in August 2020) and its Addendum (issued in December 2020). The Supplement applies to fiscal year audits beginning after June 30, 2020.

ADDRESSES: All comments to the 2021 Supplement must be in writing and received by August 30, 2021. Late comments will be considered to the extent practicable. Comments will be reviewed and addressed, when appropriate, in the 2022 Compliance Supplement. Electronic mail comments may be submitted to: *http://www.regulations.gov.* Please include ''2 CFR Part 200 Subpart F—Audit Requirements, Appendix XI—Compliance Supplement—2021'' in the subject line and the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and email address in the text of the message. Comments may also be sent to: *GrantsTeam@omb.eop.gov.*

Please note that all public comments received are subject to the Freedom of Information Act and will be posted in their entirety, including any personal and/or business confidential information provided. Do not include any information you would not like to be made publically available.

The 2021 Supplement is available online on the OMB home page at *https://www.whitehouse.gov/omb/office-federal-financial-management/.*

FOR FURTHER INFORMATION CONTACT: Recipients and auditors should contact their cognizant or oversight agency for audit, or Federal awarding agency, as appropriate. The Federal agency contacts are listed in appendix III of the Supplement. Subrecipients should contact their pass-through entity. Federal agencies should contact Gil Tran at *Hai_M._Tran@omb.eop.gov* or (202) 395–3052 or the OMB Grants team at *GrantsTeam@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: The 2021 Supplement (2 CFR part 200, subpart F, appendix XI) adds five new programs, deletes four programs and provides updates on many other programs (including the 14 programs previously included in the 2020 Addendum to the Single Audit Compliance Supplement), where necessary. The 2021 Supplement is a continuation of efforts to maximize the value of grant funding by applying a risk-based, data-driven framework that balances compliance requirements with demonstrating successful results. Consistent with the reduction in compliance areas in the 2019 Supplement, the 2021 Compliance Supplement allows for a maximum of six compliance areas and requires a review for performance reporting for 57 programs. OMB is continuing to work with Federal awarding agencies to further emphasize performance reviews and will make updates accordingly in future Supplements. The 2021 Supplement also includes guidance related to the administrative flexibilities included in Appendix 3 of OMB memorandum M–21–20 (March 19, 2021) and the revisions to 2 CFR—Grants and Agreements (published in August 12, 2020) in Part 8, Appendix VII of the Supplement. As part of the development of the audit guidance contained in the Supplement, OMB shared the draft language developed by the agencies with recipient and audit stakeholders, including the American Institute of Certified Public Accountants (AICPA), the National Association of State Auditors, Controllers and Treasurers (NASACT, the US Government Accountability Office (GAO), and agency Inspector General offices for comments. The comments were reviewed, adjudicated, and addressed by the relevant agencies and OMB. All necessary changes are reflected in the final published version. A summary of comments and OMB responses is shown below.

Audit Extension—Commenters suggested clarifications on the Single Audit extension allowed in OMB M–21–20 to be included in the Supplement Part 8, Appendix VII. OMB concurred and added information related the audit extension.

Performance Reporting Review—Commenters highlighted that there was a significant increase in the number of programs in the Supplement that require auditors to review the recipients' performance reporting requirements. Commenters suggested agencies add the key line items in the performance reports that the agencies request the auditors verify, in order to focus the auditors on the important areas for review. OMB concurred and worked with the relevant agencies to add the key line items on the performance reports in the ''Suggested Audit Procedures'' section.

2 CFR Revisions (effective November 12, 2020)—Commenters requested that the Supplement contain two separate parts B for the Allowable Costs/Cost Principles—one for the applicable cost principles prior to 2 CFR updates on November 12, 2020 and one for applicable cost principles after November 12, 2020. OMB disagreed but provided clear indication of the cost principles and areas that were revised in November 12, 2020. Additionally, the Supplement provides the link to *CFO.gov Uniform Guidance (cfo.gov)* which contains the relevant information related to the 2 CFR and its revisions, including the redlined version of the guidance, a crosswalk document, and the latest set of Frequently Asked Questions (FAQs)—*2CRF-FrequentlyAskedQuestions_2021050321.pdf (cfo.gov).*

Assistance Listing (CFDA)—Commenters noted that the term ''Assistance Listing'' is now used on the Federal Government website *Sam.gov* instead of the previous term of ''CFDA'' to describe a Federal program. OMB concurred and replaced ''CFDA'' with ''Assistance Listing'' for consistency.

American Rescue Plan Act (ARP) Programs—The audit community, including GAO, requested that the agencies provide audit guidance expeditiously for the programs created under the ARP, since funds are material and many have complex compliance and reporting requirements. OMB is working with Federal awarding agencies to identify the new ARP programs with special compliance and reporting requirements. When completed by the agencies and reviewed by OMB, these audit guides will be published on the *CFO.gov* website.

Deidre A. Harrison,

Deputy Controller.

[FR Doc. 2021–17363 Filed 8–12–21; 8:45 am]

BILLING CODE 3110–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2021–0028]

Privacy Act of 1974: Implementation of Exemptions; U.S. Department of Homeland Security/ALL–046 Counterintelligence Program System of Records

AGENCY: U.S. Department of Homeland Security.

ACTION: Final rule.

SUMMARY: The U.S. Department of Homeland Security (DHS) is issuing a final rule to amend its regulations to exempt portions of a newly established system of records titled, ''DHS/ALL–046 Counterintelligence Program System of Records'' from certain provisions of the Privacy Act. Specifically, the Department exempts portions from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: This final rule is effective August 13, 2021.

FOR FURTHER INFORMATION CONTACT: For privacy questions please contact: Lynn Parker Dupree, (202) 343–1756, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Department of Homeland Security (DHS) published a notice of proposed rulemaking in the **Federal Register**, 85 FR 80667 (December 14, 2020), proposing to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements. In concert with that rulemaking, DHS issued a new system of records notice, ''DHS/ALL–046 Counterintelligence Program System of Records'' in the **Federal Register**, 85 FR 80800 (December 14, 2020), outlining that DHS will collect and maintain records as part of the unified Counterintelligence Program across the Department.

DHS invited comments on both the Notice of Proposed Rulemaking (NPRM) and System of Records Notice (SORN).

II. Public Comments

DHS received no comments on the NPRM and comments from one organization on the SORN.

SORN

DHS received comments suggesting that (1) the scope of the proposed records system is broad and DHS components' access to records covered by the Counterintelligence Program System of Records create the risk that components would use the records system in ways that exceed their stated missions; (2) the proposed routine use exemptions are not narrowly tailored to the defined purpose of the SORN for which the records are collected, would be used to disclose records to foreign and private entities that are not subject to the Privacy Act, and would create substantial risks for potential data breaches; (3) the Counterintelligence Program System of Records creates a substantial risk of data breach since the Federal Government has demonstrated it is incapable of handling and safeguarding sensitive information; and (4) the proposed exemptions are unnecessary and limit individuals' ability to correct harmful errors, thwart DHS's public notice obligations, and permit unlimited data collection, even if unnecessary and irrelevant. After full consideration of public comments, the Department will implement the rulemaking as proposed for the reasons described in the NPRM and as described here in the final rule.

List of Subjects in 6 CFR Part 5

Freedom of information, Privacy.

For the reasons stated in the preamble, DHS amends Chapter I of Title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 6 U.S.C. 101 *et seq.;* Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. Amend Appendix C to Part 5 by adding paragraph 83 to read as follows:

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

83. The Department of Homeland Security (DHS)/ALL–046 Counterintelligence Program System of Records consists of electronic and paper records and will be used by DHS and its components. The DHS/ALL–046 Counterintelligence Program System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including the enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under; national security and intelligence activities; and protection of the President of the U.S. or other individuals pursuant to Section 3056 and 3056A of Title 18. The system of records covers information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other federal, state, local, tribal, foreign, or international government agencies.

The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(j)(2), has exempted this system from the following provisions of the Privacy Act, 5 U.S.C. secs. 552a(c)(3), (c)(4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5), (e)(8), (e)(12); (f); and (g)(1). Additionally, the Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. secs. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f). Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) and (4) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (d) (Access and Amendment to Records) because access to the records contained in this system of

records could inform the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS or another agency. Access to the records could permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension. Amendment of the records could interfere with ongoing investigations and law enforcement activities. Further, permitting amendment to counterintelligence records after an investigation has been completed would impose an unmanageable administrative burden. In addition, permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

(c) From subsection (e)(1) (Relevancy and Necessity of Information) because in the course of investigations into potential violations of federal law, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsection (e)(2) (Collection of Information from Individuals) because requiring that information be collected from the subject of an investigation would alert the subject to the nature or existence of the investigation, thereby interfering with that investigation and related law enforcement activities.

(e) From subsection (e)(3) (Notice to Subjects) because providing such detailed information could impede law enforcement by compromising the existence of a confidential investigation or reveal the identity of witnesses or confidential informants.

(f) From subsections (e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f) (Agency Rules), because portions of this system are exempt from the individual access provisions of subsection (d) for the reasons noted above, and therefore DHS is not required to establish requirements, rules, or procedures with respect to such access. Providing notice to individuals with respect to existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which individuals may access and view records pertaining to themselves in the system would undermine investigative efforts and reveal the identities of witnesses, and potential witnesses, and confidential informants.

(g) From subsection (e)(5) (Collection of Information) because with the collection of information for law enforcement purposes, it is impossible to determine in advance what information is accurate, relevant, timely, and complete.

(h) From subsection (e)(8) (Notice on Individuals) because compliance would interfere with DHS's ability to obtain, serve, and issue subpoenas, warrants, and other law enforcement mechanisms that may be filed under seal and could result in disclosure of investigative techniques, procedures, and evidence.

(i) From subsection (e)(12) (Matching Agreements) because requiring DHS to provide notice of a new or revised matching agreement with a non-Federal agency, if one existed, would impair DHS operations by indicating which data elements and information are valuable to DHS's analytical functions, thereby providing harmful disclosure of information to individuals who would seek to circumvent or interfere with DHS's missions.

(j) From subsection (g)(1) (Civil Remedies) to the extent that the system is exempt from other specific subsections of the Privacy Act.

Lynn Parker Dupree,

Chief Privacy Officer, U.S. Department of Homeland Security.

[FR Doc. 2021–17004 Filed 8–12–21; 8:45 am]

BILLING CODE 9110–9N–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 275

[FNS–2018–0043]

RIN 0584–AE64

Supplemental Nutrition Assistance Program: Non-Discretionary Quality Control Provisions of the Agricultural Improvement Act of 2018

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Interim final rule.

SUMMARY: The U. S. Department of Agriculture (the Department) is issuing this interim final rule to strengthen and improve the integrity and accuracy of the Food and Nutrition Service (FNS) Supplemental Nutrition Assistance Program (SNAP) Quality Control (QC) system by codifying statutory requirements enacted by the Agriculture Improvement Act of 2018 (2018 Farm Bill) that was signed into law on December 20, 2018.

DATES:

Effective date: August 13, 2021.

Compliance date: August 13, 2021, except for the Paperwork Reduction Act (PRA) provisions, which are delayed pending approval by the Office of Management and Budget (OMB). The Food and Nutrition Service will publish a document in the **Federal Register** announcing the compliance date.

Comment dates: Written comments on this interim final rule must be received on or before October 12, 2021 to be assured of consideration. We will consider comments on the Paperwork Reduction Act that we receive by October 12, 2021.

ADDRESSES: The Food and Nutrition Service, USDA, invites interested persons to submit written comments on this interim final rule. Comments may be submitted in writing by one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Send comments to Stephanie Proska, Branch Chief, Quality Control Branch, Program Accountability and Administration Division; Food and Nutrition Service; 1320 Braddock Place, 5th Floor; Alexandria, Virginia 22314.
- *Email:* Send comments to *SNAPQCReform@usda.gov.* Include Docket ID Number FNS–2018–0043, ''SNAP: Non-Discretionary QC provisions of Title IV of PL 115–334'' in the subject line of the message.
- All written comments submitted in response to this interim final rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the written comments publicly available on the internet via *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Stephanie Proska, Food and Nutrition Service, 1320 Braddock Place, 5th Floor; Alexandria, Virginia 22314, *SNAPQCReform@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Section 16 of the Food and Nutrition Act of 2008, as amended (FNA), each State agency is responsible for monitoring and improving its administration of SNAP and providing information from the SNAP quality control (QC) system. For QC reviews, States conduct monthly reviews of a statistically representative sample of households participating in SNAP (active cases) and households for whom participation was denied, terminated, or suspended (negative cases). These reviews measure the accuracy of SNAP eligibility and benefit determinations and ultimately serve as the basis for the SNAP payment error rate (PER), as defined in Section 16(c)(2)(A) of the FNA, and case and procedural error rate (CAPER),[1] respectively. The results of

[1] In fiscal year 2012, the procedures for reviewing cases in the negative frame, discussed later, changed to include the State's procedural processes in determining a negative case's validity. FNS has referred to the negative error rate since then as the case and procedural error rate, or CAPER, to reflect this change.

these reviews provide States with feedback on the State's administration of the program, including how their chosen policy options, waivers, and business processes affect the accuracy of their eligibility determinations.

SNAP QC has four goals, identified at 7 CFR 275.10(b), which are to provide: (1) A systematic method of measuring the accuracy of the SNAP eligibility caseload; (2) a basis for determining all SNAP error rates; (3) a timely, continuous flow of information on which to base corrective action at all levels of administration; and (4) a basis for establishing State agency liability for errors that exceed the National performance measure pursuant to Section 16(c)(1)(C) of the FNA.

Every Federal fiscal year (October through September), State agencies conduct QC reviews for two different sampling frames—the active sampling frame and the negative sampling frame. For the active frame, States review a sample of their overall participating SNAP households (those receiving SNAP benefits). This QC review consists of a detailed examination of household non-financial and financial circumstances including income, resources, and deductions to determine whether benefits were accurately authorized by State eligibility offices for cases in the active frame. For the negative frame, reviewers review a statistical sample of cases that were denied, suspended, or terminated to determine not only their accuracy, but also if the State agency followed the correct procedures according to SNAP regulations.

After State agencies submit their completed QC reviews to the Federal government, Federal staff select and review a sub-sample of cases from the active and negative frames to verify the accuracy of the States' QC review findings. A regression analysis is then performed utilizing both the Federal and State data to calculate national and State error rates. FNS also uses the data gathered through the QC review process for program analysis.

Beginning in calendar year 2015, FNS conducted integrity reviews of all 53 SNAP State agencies nationwide and USDA's Office of Inspector General (OIG) conducted an audit on the SNAP QC review process.[2] The integrity reviews and the OIG audit found there were integrity issues with the data submitted by State agencies. In short, the majority of States (42 of 53) were underreporting QC errors in the active frame. In response to these findings, FNS undertook significant measures, explained in more detail later in this preamble, to improve training and strengthen controls over the QC process. In some cases, the Department of Justice (DOJ) entered into settlement agreements with States for the underreporting of SNAP QC errors in violation of Federal law.

On December 20, 2018, the President signed into law the Agriculture Improvement Act of 2018 (2018 Farm Bill). Section 4013 of the 2018 Farm Bill included requirements to reform the SNAP QC system in order to further improve the integrity of the system and accuracy of the data it produces. These requirements build upon the Departmental and DOJ actions taken to address integrity concerns raised by FNS and OIG reviews.

The 2018 Farm Bill included changes in three sections of the legislation that required SNAP to update its regulations accordingly. Section 4013(a) of the 2018 Farm Bill requires ''All [State SNAP] records, and the entire information systems in which records are contained . . .'' be made available for inspection and audit by the Secretary. Section 4013(b) of the 2018 Farm Bill required the Department issue an interim final rule that: (1) Ensures the QC system produces valid statistical results; (2) provides for the oversight of contracts entered into by a State to improve payment accuracy; (3) ensures the accuracy of data collected in the QC system; and (4) provides for the evaluation of the integrity of the QC process for a minimum of 2 State agencies per fiscal year, to the maximum extent practicable. The regulations within this rule reflect those requirements.

Good Cause Analysis

Pursuant to the Administrative Procedure Act (APA), notice and comment are not required prior to the issuance of a rule if an agency, for good cause, finds that ''notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' (5 U.S.C. 553(b)(B)). USDA recognizes that courts have held that the good cause exception to notice and comment rulemaking is to be narrowly construed and only reluctantly countenanced.

As a result of the statutory requirement for the Department to promulgate an interim final rule addressing these issues, the Department finds for good cause that notice and public comment is unnecessary and contrary to the public interest for this rule. This interim final rule and the regulatory amendments described below address provisions of Sections 4013(a), as well as Section 4013(b) of the 2018 Farm Bill that USDA was directed by Congress to promulgate via interim final rule.

Subpart A—Administration

Use of Third-Party Contractors

Upholding the integrity of the QC system is critical to the Department's responsibility for improper payment reporting and proper stewardship of taxpayer funds. Evaluation of the SNAP caseload and the benefits issued must be reliable in order to accurately measure SNAP payment errors. In their respective reviews, FNS, OIG, and DOJ found that a majority of States used third-party contractors at various times over the preceding 10 years to provide regulatory and policy advice on how to conduct SNAP QC reviews in their State. It was also found that States following the advice of contractors often underreported errors in active QC case reviews. Advice that contributed to the underreporting of errors included training State QC reviewers to document cases inappropriately, organizing committees that focused on developing methods to mitigate errors and underreport existing payment errors to FNS, and withholding information or disposing of cases contrary to SNAP regulations and established policy.

On January 20, 2016, FNS issued a policy memorandum [3] on the use of third-party contractors for QC purposes to address these issues. FNS issued this memorandum based the understanding that it is within the agency's regulatory authority to clarify policy. While the memorandum provided timely and clear guidance to States in response to a critical integrity issue, this interim final rule will ensure that the expectations are explicit. The memorandum clarified the appropriate use of contractors in the QC process and established procedures regarding the use of contractors to help ensure that activities performed under the contract are in accordance with Federal regulations and policies. The memorandum required a State to notify FNS of its intent to enter into a contract for the purposes of training State QC reviewers on SNAP regulations, policies, or manuals to improve payment accuracy, and to provide a copy of its contract and all deliverables to FNS. The memorandum emphasized that any activities or deliverables not complying with Federal regulations and policy would not be eligible for Federal reimbursement, as provided by Section

[2] *https://www.usda.gov/oig/webdocs/27601-0002-41.pdf.*

[3] *https://www.fns.usda.gov/snap/integrity-snap-quality-control-system.*

16(a) of the FNA, which authorizes the Secretary of Agriculture to pay each State agency 50 percent of all administrative costs involved in each State agency's operation of SNAP. The memorandum also stipulated that FNS be allowed attend any training sessions or meetings that discussed individual QC cases and required that the State document any discussions about individually sampled cases within the QC record for subsequent review and auditing purposes.

Subsequent to the issuance of this guidance, the 2018 Farm Bill directed the Department to issue interim final regulations to provide for the oversight of contracts entered into by a State agency for the purpose of improving payment accuracy. As a result, the Department is codifying at § 275.2(c) the requirements on the oversight of contracts previously set forth by FNS in the 2016 policy memorandum. This paragraph at § 275.2(c) will also codify the 2018 Farm Bill requirement at Section 4013(b) that any person who knowingly submits, or causes submittal of, false information in carrying out the QC system be debarred in accordance with procedures outlined in 2 CFR part 417. This particular provision regarding debarment, codified through this interim final rule, was self-executing upon enactment of the 2018 Farm Bill.

These provisions associated with third party contractors under 7 CFR 275.2(c)(1) will be effective upon OMB's approval of the information collection associated with this activity.

State Systems Access

Section 4013(a) of the 2018 Farm Bill required that all State agency records and the systems in which those records are contained be made available to the Department for QC purposes. To ensure the accuracy of data collected in SNAP QC and to allow for independent oversight of program administration, FNS must have access to State agency records and the systems in which those records are contained; this includes remote access. While mandatory FNS access to State computer systems for QC purposes has existed since the current QC system was implemented, it is necessary to specifically include remote access in this requirement to ensure Federal staff has the tools necessary to conduct thorough QC re-reviews from their duty stations. While some State agencies have already provided remote access to their systems, it has been difficult to gain access in some states due to technological and security challenges. These challenges include issues concerning equipment and firewalls as well as the fact that some State systems do not include a user role that allows access only to SNAP information.[4] A new paragraph at § 275.2(d) will require FNS have access, including remote access, to all State agency records and systems in which those records are contained. The Department believes this provision will enable State agencies to make the necessary changes to allow remote access to State computer systems for SNAP QC purposes, and therefore help ensure the accuracy of the collected data through the QC system. FNS will continue to work with States collaboratively to establish data sharing and system integrity agreements to facilitate the required systems access. This provision is effective upon publication of this rule.

Federal Monitoring—Reviews of State Agency's Quality Control System

The 2018 Farm Bill further requires FNS to ensure that the integrity of the QC system is reviewed in at least two State agencies per fiscal year to the maximum extent practicable. As a result, the Department is adding a new paragraph at § 275.3(c) to use the existing management evaluation process to provide for the review of at least two State agency QC systems per year. The paragraphs currently located at § 275.3(c) and (d) are being appropriately re-designated as § 275.3(d) and (e), respectively. This provision is effective upon publication of this rule.

Social Security Administration (SSA) Processed Cases

This rule will also ensure statistically valid results and improve the accuracy of QC data collected by State agencies by requiring that cases processed by the Social Security Administration (SSA) are included in the error rate. Currently, SSA processes applications for around 50,000 SNAP cases a year. Less than one-tenth of a percent of cases sampled for QC review are processed by SSA. Current regulations require SNAP cases that are processed by SSA to be reviewed according to standard procedures; longstanding FNS policy exempts these cases from inclusion in the error rates. SNAP regulations at 273.2(k)(l) provide two options for SSA involvement in the certification process for SNAP beneficiaries, which are designed to simplify the SNAP application process for households applying for and receiving Supplemental Security Income. The first option is for the SSA office itself to complete and forward applications to the local SNAP office, and the second is for the local SNAP agency to outstation a worker at the SSA office. Both processes require the SNAP agency to make the final determination on the application, meaning that even when SSA participates in completing the application, the State agency must clarify unclear information and ensure the benefit determination and allotment amount are correct. Since the SNAP agency is responsible for finalizing and processing applications received at SSA offices, including these cases in the error rate would ensure this population of households is part of the improper payment measurement. This would improve the accuracy of QC data collection and reporting methods. FNS believes that excluding these cases from the error rate is inconsistent with current Federal improper payment requirements and intends to correct this inconsistency by requiring SSA processed cases be included in the SNAP error rate. For these reasons, the Department is amending the following sections in 7 CFR to clarify that SSA processed cases shall be treated in the same manner as other SNAP cases for QC purposes: newly redesignated 275.11(g); and 275.12(h), 275.13(f), 275.21(d), and 275.23(b)(1). This provision is effective upon publication of this rule.

Record Retention

To further ensure the accuracy of QC data collected by State agencies, this interim final rule will also provide more detail on what records must be retained for QC case files. Past QC integrity management evaluation reviews conducted by FNS found that many State agencies misunderstood SNAP QC record retention requirements, including the essential document types that must be reported and retained. In addition to these FNS reviews, the OIG audit of the QC error rate process and the FNS completion rate study[5] each discovered intentional and unintentional instances of State agencies leaving documentary evidence out of the case file. As a result, Federal QC reviewers had insufficient information to review such cases and determine whether the information used

[4] State systems contain information on participants in a multitude of different programs, each of which can have (as some currently do) statutory and regulatory language prohibiting the disclosure of such information outside of said program. As such, the State systems must be able to limit user access to SNAP information only before sharing the system with FNS for SNAP QC purposes to ensure compliance with federal law.

[5] On January 11, 2016, FNS published a study, Enhancing SNAP Quality Control Completion Rates, that examined the factors contributing to incomplete reviews of cases and described best practices associated with high SNAP QC completion rates.

in the State case determinations was accurate. When State agencies do not properly retain such documentary records, FNS cannot adequately confirm data accuracy and integrity.

The Department has concluded that the existing regulations lack sufficient specificity for States to determine which QC-related records must be maintained for the required duration of three years post fiscal closure, which is when the error rate is issued for most States; for States in liability status, three years post fiscal closure begins on the date the State fulfills all requirements to close its liability. In an effort to strengthen the understanding of which records States must maintain and to increase the integrity of the QC system and quality of data, the Department is amending the regulatory language at § 275.4(c) to provide more comprehensive detail, including specifying that all correspondence with the household and all case notes, digital or otherwise, be included in the QC case file, among other requirements. This will help ensure the accuracy of QC data collected by State agencies. This provision is effective upon publication of this rule.

Subpart F—Responsibilities for Reporting on Program Performance

Quality Control Review Reports—Individual Cases

In the course of conducting a QC review, FNS requires State agencies to accurately record, document, summarize, and code household circumstances, which includes completing the review forms associated with active and negative QC reviews, to ensure the accuracy of the data collected. Current regulations at § 275.21(b) require States to submit ''edited'' findings for both Form FNS–380–1 and Form FNS–245. When these QC rules were originally written, the ''edits'' were related to the capability of computer systems to communicate with one another. Until computers were able to communicate more directly, without a dial up connection, it was common practice for States to review the files uploaded to FNS to ensure the data they submitted was consistent with data received on the other end. When the received data did not match what was sent, the State had to ''edit'' those mismatched fields to ensure the data was accurate.

As computer technology has dramatically improved since this provision was written and communication errors are now the exception rather than the norm, it is necessary to remove this reference to ''edited'' data to ensure FNS is clear that States are expected to submit thorough and final versions of the required QC forms to FNS.

FNS, OIG and DOJ found that, in some cases, States interpreted § 275.21(b) to allow significant editing of the facts of cases under review before submission to FNS and used that interpretation to misrepresent cases that contained payment errors and to artificially lower the reported State error rate. Since ''editing'' findings is an integrity concern and the original intent is no longer of concern due to advancements in technology, the Department is amending the language in § 275.21(b) by removing the term, ''edited'' from regulatory text to better ensure the accuracy of the data collected. FNS will continue to provide a process for States to correct typos and data entry errors in their submissions. This provision is effective upon publication of this rule.

In addition, the regulation at § 275.21(b) does not currently require States to include Form FNS–380, Worksheet for QC reviews, upon submission of QC cases to FNS. Currently, States are required to use the Form FNS–380 to record their notes and observations over the course of completing their review, but are only required to submit the form in the event that a case is selected for Federal sub-sample. Requiring the Form FNS–380 be submitted for all cases, regardless of whether the case was included in the Federal sub-sample, will provide greater information about SNAP households to FNS for program analysis purposes and improve the consistency of documentation across cases by ensuring States submit all pertinent information before knowing a case has been selected for Federal review. The Department believes requiring that the form be thoroughly documented and submitted will enable case reviewers to fully understand the circumstances of the case, final finding, and disposition, and the quality of the State QC reviewers' submitted reviews will be improved. These changes will help to ensure more statistically valid results and will help to ensure the accuracy of QC data collected. As a result, § 275.21(b) is modified accordingly. This provision is effective upon publication of this rule.

Procedural Matters

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Department has developed this rule in accordance with these orders.

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this interim final rule is significant and was accordingly reviewed by the Office of Management and Budget (OMB).

Regulatory Impact Analysis

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). USDA does not anticipate this interim final rule is likely to have an economic impact of $100 million or more in any one year, and therefore, does not meet the definition of ''economically significant'' under Executive Order 12866.

The provisions in this rule are not anticipated to have any impacts on SNAP participation or benefit issuance (transfers) and most are not expected to have measurable impacts on State Agencies or the Federal Government. For example, the cost estimate for the burden associated with the new reporting provisions do not exceed a total of $110 combined for all State agencies per year. The interim final provisions implement statutory changes included in the 2018 Farm Bill; most of these statutory changes reflect policies and practices that are already in place and thus are not a substantive change from current practice. For example, requiring access to State computer systems for QC purposes is existing policy that has been in place since the current QC system was implemented. While this interim final regulation would clarify that FNS must have remote access to State computer systems, this requirement is expected to have minimal impact on State administrative expenses. Currently 21 States already provide remote access to their systems. In 17 of these States there was no cost associated with allowing FNS access (other than Federal staff time to resolve firewall issues). In the remaining 4 States there was a small cost for enabling remote access ($200 for licensing in one State and $3000 for a dedicated laptop used to access all 3 of the other States, or an average of $800

per State). At $800 per State, the remote access requirement is expected to result in one-time costs of about $25,600 for the remaining 32 States.

Similarly, existing policy requires a State to notify FNS of its intent to enter into a contract for the purposes of training State QC Reviewers (SQCRs), to provide a copy of its contract and all deliverables to FNS, and any contractor activities or deliverables not complying with Federal regulations and policy are not eligible for Federal reimbursement. Current policy also requires that the State document any discussions about individually sampled cases within the QC record for subsequent review and auditing purposes.

In addition to codifying the existing requirement to document discussion about individually sampled cases, this rule places additional requirements if the State discusses individual sampled cases with a contractor. If the discussion occurs orally, FNS must be given notice 24 hours in advance of the discussion and must be allowed to participate in the discussion. If the discussion occurs in writing, the State must ensure that FNS is copied on all written correspondence discussing individual sampled cases. FNS estimates this new notification requirement will affect 5 State agency respondents once per year.

Costs:

The Department anticipates minimal costs associated with this rule. As noted above, the rule provisions primarily implement activities that are current policies and practice.

FNS does anticipate a small increase in reporting burden for State agencies associated with the requirement that States notify FNS in advance or copy FNS on written correspondence when the State discusses individual sampled cases with a contractor. As described in the Paperwork Reduction Act section of this rule, FNS anticipates that 5 States will be required to submit such notification once per year, for an additional 0.4 hours in reporting burden annually. Because FNS has already addressed situations where States used contractors improperly, we expect States to discuss individual cases with contractors only on rare occasions.

No additional Federal costs are anticipated; any staff time devoted to these activities will be part of the normal duties of Federal staff.

Benefits:

The Department anticipates that these interim final provisions will improve Federal oversight of State QC systems and improve the integrity of State-reported QC data used to determine SNAP error rates.

Transfers:

The Department does not anticipate any changes in transfers associated with this rule.

Alternatives:

The 2018 Farm Bill required that the Department implement specific changes to current QC operations and eliminated performance bonus payments to States. Therefore, no alternatives were considered.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Agencies to analyze the impact of rulemaking on small entities and consider alternatives that would minimize any significant impacts on a substantial number of small entities. Rules that are exempt from notice and comment are also exempt from the Regulatory Flexibility Act requirements, including conducting a regulatory flexibility analysis, when among other things the agency for good cause finds that notice and public procedure are impracticable, unnecessary, and contrary to the public interest.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as 'not major', as defined by 5 U.S.C. 804(2).

Executive Order 12372

SNAP is listed in the Catalog of Federal Domestic Assistance under Number 10.551. For the reasons set forth in the Final Rule codified in 7 CFR part 3015, subpart V and the related Notice (48 FR 29115), this Program is excluded from the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under Section (6)(b)(2)(B) of Executive Order 13121.

The Department has considered the impact of this interim rule on State and local governments and has determined that this rule does not have federalism implications. Therefore, under Section 6(b) of the Executive Order, a federalism summary is not required.

Executive Order 12988, Civil Justice Reform

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This rule is not intended to have retroactive effect unless so specified in the Effective Dates section of the final rule. Prior to any judicial challenge to the provisions of the final rule, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed the interim final rule, in accordance with the Department Regulation 4300–004, Civil Rights Impact Analysis, to identify and address any major civil rights impacts the interim final rule might have on minorities, women, and persons with disabilities. A comprehensive Civil Rights Impact Analysis (CRIA) was conducted on the interim final rule, including an analysis of data and provisions contained in the interim final rule. The CRIA outlines outreach and mitigation strategies to lessen any possible civil rights impacts. The CRIA concludes the interim final rule will impact State agencies by including cases processed by SSA in the error rate determination; however, this will not change the rate at which these households are selected for review. The Department finds that the implementation of mitigation strategies and monitoring by the FNS Civil Rights Division and FNS SNAP may lessen any impacts. SNAP has procedures in place to provide special accommodations for the QC review should elderly persons and individuals with disabilities request accommodation. These accommodations are described at 7 CFR 275.12(c)(1), which provides that if there is a hardship to the household in attending the QC interview, the reviewer must interview the household's authorized representative if they have one or go to the household's home. Additionally, FNS SNAP will continue to work with State agencies to ensure they are aware of their responsibility to provide special accommodation for the elderly and disabled persons during QC reviews. If necessary, the FNS Civil Rights Division will propose further mitigation and outreach strategies to alleviate impacts that may result from the implementation of the interim final rule.

Executive Order 13175

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments, or proposed legislation. Additionally, other policy statements or actions that have substantial direct effects on one or more Indian Tribes, the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes also require consultation. This regulation discloses there are no tribal implications associated with this rule. FNS attended a tribal consultation meeting on May 1, 2019, in Washington, DC where the changes to this rule were explained. No questions or concerns were brought to FNS's attention about this rule by any tribal leaders at the meeting. If a tribe requests consultation in the future, FNS will work with the Office of Tribal Relations to ensure meaningful consultation is provided.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR 1320), requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current, valid OMB control number.

In accordance with the Paperwork Reduction Act of 1995, this interim final rule contains information collections that are subject to review and approval by the Office of Management and Budget; therefore, FNS is submitting for public comment the changes in the information collection burden that would result from adoption of the proposals in the rule. The agency is seeking a three-year renewal date for both OMB control numbers. Once OMB approves these burden requirements associated with OMB Control Numbers: 0584–0074 and 0584–0303, the agency plans to publish separate notices in the **Federal Register** announcing OMB's approval.

We are revising two existing burden inventories for this rulemaking. The current burden inventories affected are Worksheet for the Supplemental Nutrition Assistance Program Quality Control Reviews (FNS–380) OMB Control Number: 0584–0074, expiration date 04/30/2023 and Supplemental Nutrition Assistance Program 275 QC Regulations OMB Control Number: 0584–0303, expiration date 1/31/2024 respectively. These changes are contingent upon OMB approval under the Paperwork Reduction Act of 1995 and as such are including two 60 day notices for comment on the affected collections.

Comments on both the information collections in this interim final rule must be received by October 12, 2021.

Send comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FNS, Washington, DC 20503, Fax 202–395–7285, or email to *oira_submission@omb.eop.gov.* Please also send a copy of your comments to any of the following: via mail to Stephanie Proska, Branch Chief, Quality Control Branch, Program Accountability and Administration Division, 1320 Braddock Place, 5th Floor; Alexandria, Virginia 22314; via fax to the attention of Stephanie Proska at 703–305–0928; or via email to *SNAPHQ-WEB@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically. All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record. For further information, or for copies of the information collection requirements, please contact Stephanie Proska at the address indicated above or email *SNAPHQ-WEB@fns.usda.gov.*

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the Agency's functions, including whether the information will have practical utility; (2) the accuracy of the Agency's estimate of the proposed information collection burden, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to these requests for comment will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Title: Worksheet for the Supplemental Nutrition Assistance Program's Quality Control Reviews.

Form Number: FNS 380.

OMB Control Number: 0584–0074.

Expiration Date: April 30, 2023.

Type of Request: Revision of a currently approved collection due to rulemaking.

Abstract: Section 16 of the Food and Nutrition Act of 2008 provides the legislative basis for the operation of the Quality Control (QC) system. Part 275, Subpart C, of SNAP regulations implements the legislative mandates found in Section 16. Regulations at 7 CFR 275.1, 275.14(d) and 275.21(a) and (b)(1) provide the regulatory basis for the QC reporting requirements.

Section 11(a) of the Food and Nutrition Act of 2008 provides the legislative basis for the recordkeeping requirements. SNAP regulations, at 7 CFR 272.1(f), specify that program records must be retained for three years from the month of origin. Regulations at 7 CFR 275.4 specifically address record retention requirements for form FNS–380.

Form FNS–380, is a SNAP worksheet used to determine eligibility and benefits for households selected for review in the QC sample of active SNAP cases. This form provides a systematic means of aiding the State's Quality Control Reviewer in analyzing the case record, planning and doing field investigation and gathering, comparing, analyzing and evaluating data.

Due to this interim-final rulemaking, the FNS 380 form must include a new State agency respondent burden for a new requirement at 7 CFR 275.2(c)(1)(v). The Department will require that if the State discusses individual sampled cases with a contractor, the State must document, within the case file, the contents of the discussion and any action taken by the State as a result of the discussion. If the discussion occurs orally, FNS must be given notice 24 hours in advance of the discussion and must be allowed to participate in the discussion. If the discussion occurs in writing, the State must ensure that FNS is copied on all written correspondence discussing individual sampled cases. FNS estimates this new notification requirement will affect 5 State agency respondents at least one time per year for a total burden of 5 minutes (0.0835 hour) per response, estimating an additional 25 minutes (0.40 hour) to the current information collection. No additional recordkeeping requirements are necessary.

We estimate the total reporting burden for the collection of information to support SNAP QC as 405,995.67 hours. This includes approximately 8.48 hours for State Agencies to analyze each household case record including planning and carrying out the field investigation; gathering, comparing,

analyzing and evaluating the review data and forwarding selected cases to the Food and Nutrition Service for Federal validation, totaling approximately 382,173.44 hours for the entire caseload. We also include an average interview burden of 30 minutes (0.5 hours) for each household, creating a reporting burden for them for 22,748.50 hours. The total reporting burden for the affected public is 404,921.94 hours. Additionally, we estimate the recordkeeping burden per record for the State Agencies to be 1.4 minutes (0.0236 hours), thereby making the recordkeeping burden associated with this information collection to be 1,073.73 hours. There is no recordkeeping requirement for households. The total estimated reporting and recordkeeping burden for this collection is 405,995.67 hours.

Reporting Burden Annual Estimates for OMB Control Number 0584–0074

Affected Public: State, Local and Tribal Government and Individuals and Households.

Estimated Number of Respondents: 45,550 (53 State Agencies and 45,497 Individuals/households).

Estimated Number of Responses per Respondent: 4,293.24 (4,292.24 for State agencies and 1 per individual/household).

Estimated Total Annual Responses: 272,985.95 (227,488.95 for State agencies and 45,497 from individuals and households).

Estimated Time per Response: 8.98 hours (8.48 hours for State agencies and .5 hour for individuals and households).

Estimated Total Burden Response Hours: 404,921.94 (382,173.44 from State agencies and 22,748.50 from individuals/households).

Recordkeeping Burden Annual Estimates for OMB Control Number 0584–0074

Number of Record Keepers: 53.

Number of Records per Record Keeper: 858.43 Records.

Estimated Number of Records/Response to Keep: 45,497 Records.

Recordkeeping time per Response: .0236 hours.

Total Estimated Recordkeeping Burden Hours: 1,073.73 hours.

Estimated Total Annual Reporting and Recordkeeping Burden on Respondents: 405,995 hours.

This information collection request associated with OMB Control Number: 0584–0074 reflects a difference of +0.40 hour due to program changes for rulemaking.

Reg. section	Affected public	Description of activity	Estimated number of respondents	Estimated responses per respondent	Revised total annual responses	Revised number of burden hours per response	Revised estimated total burden hours	Previous submission total hours	Difference due to program changes	Difference due to adjustments
Reporting Burden for State Agencies FNS 380, OMB 0584–0074										
275.2(c)(1)(v)	SA	Notification to discuss individual cases.	5	1	5	0.08	0.4	n/a	0.40	n/a
275.12 (b)	SA	Household Case Record Review	53	858.43	45,496.79	3	136,490.37	136,490.37	0.00	0.00
275.12 (c)	SA	Field investigation	53	858.43	45,496.79	3.5	159,238.77	159,238.77	0.00	0.00
275.12 (c)(1)	SA	Personal interviews	53	858.43	45,496.79	0.5	22,748.40	22,748.40	0.00	0.00
275.12 (b)	SA	Variance identification	53	858.43	45,496.79	0.9	40,947.11	40,947.11	0.00	0.00
275.12 (b)	SA	Error analysis	53	858.43	45,496.79	0.5	22,748.40	22,748.40	0.00	0.00
State Agencies (SA) Reporting Burden—Subtotals.										
53	4,292.24	227,488.95	8.48	382,173.44	382,173.04	0.40	0.00			
Reporting Burden for Individuals/Households FNS 380, OMB 0584–0074										
275.12 (c)(1)	Individual/Households.	Personal interviews	45,497	1	45,497	0.5	22,748.50	22,748.50	0.00	0.00
Individuals/Households (I/H) Reporting Burden—Subtotals.										
45,497	1	45,497	0.5	22,748.50	22,748.50	0.00	0.00			
Grand Totals Reporting Burden.	45,550.00	4,293.24	272,985.95	8.98	404,921.94	404,921.54	0.40	0.00		

RECORDKEEPING BURDEN FOR STATE AGENCIES FNS 380, OMB 0584–0074

Reg. section	Affected public	Description of activity	Estimated number of respondents	Estimated responses per respondent	Revised total annual responses	Revised number of burden hours per response	Revised estimated total burden hours	Previous submission total hours	Difference due to program changes	Difference due to adjustments
275.4	State Agencies	Record Retention	53	858.43	45,497	0.0236	1,073.73	1,073.73	0.00	0.00
Overall Grand Total Reporting SA & I/H and Recordkeeping for SA.										
45,550.00	6.99	318,482.95	9.00	405,995.67	405,995.27	0.40	0.00			

* * * * *

Action: 60 day Notice.

Summary: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this information collection in this interim final rule. This collection is a revision of a currently approved information collection request.

Dates: Written comments must be received on or before October 12, 2021.

Send Comments to: The Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FNS, Washington, DC 20503, Fax 202–395–7285, or email to *oira_submission@omb.eop.gov.* Please also send a copy of your comments to one of the following: via mail to Stephanie Proska, Branch Chief, Quality Control Branch, Program Accountability and Administration Division, 1320 Braddock Place, 5th Floor; Alexandria, Virginia 22314; via fax to the attention of Stephanie Proska at 703–305–0928; or via email to *SNAPHQ-WEB@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically. All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record. For further information, or for copies of the information collection requirements, please contact Stephanie Proska at the address indicated above or email *SNAPHQ-WEB@fns.usda.gov.*

Supplementary Information

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Supplemental Nutrition Assistance Program (SNAP).

Form Number: FNS 74 A and FNS 74B.

OMB Number: 0584–0303.

Expiration Date: January 31, 2024.

Type of Request: Revision of a currently approved collection.

Abstract: Section 16 of the Food and Nutrition Act of 2008, as amended, provides the legislative basis for the operation of the SNAP QC system. Part 275, Subpart C, of SNAP regulations implements the legislative mandates found in Section 16. Section 11(d) of the Food and Nutrition Act of 2008, as amended (the Act), requires each State agency administering SNAP to submit a plan of operation specifying the manner in which the program is conducted and Section 11(e) of the Act authorizes the inclusion of other provisions as required by regulation. In Part 275, due to this interim final rulemaking there will now be five components of the Quality Control (QC) system that are covered in this required information collection. They are: (1) The sampling plan; (2) Third party contractors (new requirement); (3) the arbitration process; (4) the good cause process; and (5) QC-related New Investments.

Each State agency is required to develop a sampling plan that demonstrates the integrity of its case selection process. The QC system is designed to measure each State agency's payment error rate and case and procedural error rate based on a statistically valid sample of SNAP cases. A State agency's payment error rate represents the proportion of cases that were reported through a QC review as being ineligible, as well as the proportion of SNAP benefits that were either overissued or under-issued to SNAP households. A State agency's case and procedural error rate represents the correctness of a proportion of cases that were measured in a QC review in which the State agency took an action to deny an application or suspend or terminate the benefits of a participating household. It also includes the accuracy of measuring a State's compliance with Federal procedural requirements for those actions, which include the timeliness of the action and adherence to notice requirements.

Due to this interim-final rulemaking, the QC system will require States to notify FNS about its intent to hire third party contractors for QC purposes, send FNS the signed contracts that are awarded, send FNS information on the third party contractor's completed deliverables to FNS, and notify FNS of training sessions that will be hosted by 3rd party contractors in the event the State agency intends to request federal reimbursement for administrative expenses associated with the third party contract.

The QC system also contains procedures for resolving differences in review findings between State Agencies and FNS. This is referred to as the arbitration process. As part of the arbitration process, State agencies must defend, in writing, their disagreement with the Federal re-reviewer's finding or disposition of a case and submit their defense to the arbitrator for a decision to be made on their disagreement. Due to this interim-final rulemaking, the regulatory reference is being updated to the revised designation of 7 CFR 275.2(d)(4).

The QC system also contains procedures that provide relief for State agencies from all or a part of a QC liability when a State agency can demonstrate that a part or all of an excessive error rate was due to an unusual event that had an uncontrollable impact on the State agency's payment error rate. This is referred to as the good cause process.

Finally, when a State agency is unable to demonstrate that a part or all of an excessive error rate was due to an unusual event that had an uncontrollable impact on the State agency's payment error rate and chooses to settle with FNS by investing fifty percent of their total QC liability using new State agency funds into the SNAP program to target the root causes of their errors, the State agency must submit a new investment plan and, after approval, new investment progress reports every six months until the plan is complete.

Note: The ability for a State agency to settle its error rate related liability is described in Section 16(c) of the Food and Nutrition Act of 2008, as amended.

Burden for the QC system includes reporting and recordkeeping burden for State agencies to create a QC sampling plan, notify and submit the required information regarding the use of third party contractors to FNS, and participate in the arbitration, good cause, new investment plan and new investment progress report processes.

The requested extension of unchanged estimates and revisions for the reporting burdens due to new requirements for each component are as follows: (1) The estimated annual reporting burden associated with the QC sampling plan is 1,060 hours, no change from the current collection; (2) the four new annual collection estimates for reporting burden associated with the notifications and submissions activities of third party contractors combined estimates is 3.99 hours; (3) the estimated annual reporting burden associated with arbitration is 1,224 hours, no change from the current collection; (4) The estimated annual reporting burden associated with the good cause process

is 160 hours, no change from the current collection; (5) The estimated annual reporting burden associated with the new investment plan is 288 hours, no change from the current collection-no 74A form changes either; and finally (6) The estimated annual reporting burden associated with the new investment progress report is 90 hours, no change from the current collection-no 74B form changes, either.

We are requesting 2,825.99 estimate annual reporting burden hours. This total includes the current estimate for this requested total estimated reporting burden for the QC system is 2,822.00, plus an increase of 3.99 hours due to program changes for this rulemaking.

The requested annual recordkeeping burden associated with the QC sampling plan remains at 1.25 hours per year. No recordkeeping is required for the third party contractor provisions, since states have their own rules for recordkeeping State contracts. The annual recordkeeping burden associated with arbitration is 0.8496 and the good cause process burden is 0.0236 hour, both remain the same as the current collection. The estimated recordkeeping burden for the QC-related new investment plans remains at 0.0214 hours and the estimated recordkeeping burden for the QC-related new investment progress reports remains at 0.4248 hours.

The burden for recordkeeping has remained at 2.7612 hours. As a result, the overall annual reporting and recordkeeping burden for the QC system, as proposed by this notice, increased from 2135.76 hours to 2,828.75 hours due to the interim-final rule provisions adding reporting requirements related to State agency use of third party contractors.

Affected Public: 53 State, Local and Tribal Government.

Reporting Burden Annual Estimates for OMB Control Number 0584–0303

Affected Public: State, Local and Tribal Government.

Estimated Number of Respondents: 53 State Agencies.

Estimated Number of Responses per Respondent: 2.4339.

Estimated Total Annual Responses: 129.

Estimated Time per Response: 21.906899 hours.

Estimated Total Burden Hours: 2,825.99 hours.

Recordkeeping Burden Annual Estimates for OMB Control Number 0584–0303

Number of Record Keepers: 53.

Number of Records per Record Keeper: 117 Records.

Estimated Number of Records/ Response to Keep: 2.2075 Records.

Recordkeeping Time per Response: 0.118 hours.

Total Estimated Recordkeeping Burden Hours: 2.7612 hours.

Estimated Total Annual Reporting and Recordkeeping Burden on Respondents: 2,828.75 hours.

This information collection request associated with OMB Control Number: 0584–0303 reflects an increase of 3.99 hours due to program changes for rulemaking.

275 REGS REPORTING OMB 0584–0303

Reg. section	Affected public	Description of activity	Estimated number of respondents	Estimated responses per respondent	Revised total annual responses	Revised number of burden hours per response	Revised estimated total burden hours	Previous submission total hours	Difference due to program changes	Difference due to adjustments
275.11(a)(1)–(a)(2)	State Agencies	Sampling Plan	53	1	53	20	1,060	1,060	0	0
275.2(c)(1)(i)	State Agencies	Use of 3rd Party Contractors-Notification of intent to hire.	3	1	3	0.25	0.75	0	0.75	0
275.2(c)(1)(ii)	State Agencies	Use of 3rd Party Contractors-Submission of signed contract and tasks.	3	1	3	0.5	1.5	0	1.5	0
275.2(c)(1)(iii)	State Agencies	Use of 3rd Party Contractors-Submission of completed deliverables.	3	1	3	0.5	1.5	0	1.5	0
275.2(c)(1)(iv)	State Agencies	Use of 3rd Party Contractors-Notification of training sessions.	3	1	3	0.08	0.24	0	0.24	0
275.2(d)(4)	State Agencies	Arbitration Process	12	3	36	34	1,224	1,224	0	0
273.23(f)	State Agencies	Good Cause Process	1	1	1	160	160	160	0	0
275.23(h)	State Agencies	New Investment Plan Template Form FNS 74 A.	9	1	9	32	288	288	0	0
275.23(h)(4)	State Agencies	New Investment Progress Report Template Form FNS 74 B.	9	2	18	5	90	90	0	0
SUB-TOTAL REPORTING BURDEN.										
53	2.433962264	129	21.90689922	2,825.99	2,822	3.99	0			

275 RECORDKEEPING OMB 0584–0303

Reg. section	Affected public	Description of activity	Estimated number of respondents	Estimated responses per respondent	Revised total annual responses	Revised number of burden hours per response	Revised estimated total burden hours	Previous submission total hours	Difference due to program changes	Difference due to adjustments
275.4	State Agencies	Sampling Plan Record Retention.	53	1	53	0.0236	1.2508	1.2508	0	0
275.4	State Agencies	Arbitration Process Record Retention.	12	3	36	0.0236	0.8496	0.8496	0	0
275.4	State Agencies	Good Cause Process Record Retention.	1	1	1	0.0236	0.0236	0.0236	0	0
275.4	State Agencies	New Investment Plan Template Form FNS 74 A Record Retention.	9	1	9	0.0236	0.2124	0.2124	0	0
275.4	State Agencies	New Investment Progress Report Template Form FNS 74 B Record Retention.	9	2	18	0.0236	0.4248	0.4248	0	0
Sub Total RECORDKEEPING.										
53	2.20754717	117	0.118	2.7612	2.7612	0	0			

Reg. section	Affected public	Description of activity	Estimated number of respondents	Number of reports annually by state	Number of total annual records	Estimated time per record	Estimated total record keeping hours	Previous submission total hours	Difference due to program changes	Difference due to adjustments
Grand Total REPORTING & RECORDKEEPING.										
53	4.41509434	234	12.08868034	2,828.7512	2,824.7612	3.99	0			

E-Government Act Compliance

The Department is committed to complying with the E-Government Act of 2002, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 7 CFR Part 275

Grant programs-social programs, Reporting and recordkeeping requirements.

Accordingly, 7 CFR part 275 is amended as follows:

PART 275—PERFORMANCE REPORTING SYSTEM

■ 1. The authority citation for part 275 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

■ 2. Amend § 275.2 by adding paragraphs (c) and (d) to read as follows.

§ 275.2 State agency responsibilities.

* * * * *

(c) *Use of third party contractors.* Any State agency procuring services of a contractor for quality control related services, including any project or training that involves the interpretation of SNAP regulations, policies, or handbooks for quality control or payment accuracy purpose, must ensure that all activities and deliverables performed by the contractor within the scope of the contract adhere to Federal law, regulations, and policies. Activities performed or deliverables provided by a contractor that are not in accordance with Federal law, regulations, or policies are unallowable SNAP administrative costs and are not eligible for Federal reimbursement.

(1) For expenses related to the hiring of a contractor for any quality control related work to qualify for SNAP administrative cost reimbursement under § 277.4(b), FNS requires the following:

(i) The State must notify FNS in writing of its intent to hire a contractor at least 30 days prior to entering into the contract to do so. The notification must include a copy of the selected contractor's complete proposal, which must receive FNS approval before the State may proceed with the procuring the contract.

(ii) Once the contract is procured, the State must submit to FNS a copy of the signed contract and documentation that outlines all tasks and deliverables to be performed or produced by the contractor.

(iii) The State must submit to FNS a copy of all deliverables, including any training materials, provided by the contractor.

(iv) The State must notify FNS of the date, time, and location of any training sessions led by the contractor at least 10 days in advance of the training. FNS shall be allowed to attend any such training session with or without providing prior notice to the State agency or the contractor.

(v) If the State discusses individual sampled cases with the contractor, the State must document, within the case file, the contents of the discussion and any action taken by the State as a result of the discussion. If the discussion occurs orally, FNS shall be given notice 24 hours in advance of the discussion and shall be allowed to participate in the discussion. If the discussion occurs in writing, the State must ensure that FNS is copied on all written correspondence discussing individual sampled cases.

(2) Copies of documentation and notices required in paragraph (c)(1) of this section must be provided to the appropriate FNS Regional SNAP Director.

(3) In accordance with the non-procurement debarment procedures under 2 CFR part 417, or successor regulations, FNS shall debar any person that, in carrying out the quality control system, knowingly submits or causes to be submitted false information to FNS.

(4) Compliance date: Paragraph (c)(1) of this section contains information-collection requirements. Compliance with paragraph (c)(1) will not be required until this paragraph (c)(4) is removed or contains a compliance date, after review of such requirements by the Office of Management and Budget pursuant to the Paperwork Reduction Act.

(d) *FNS Access to State Systems.* Subject to data and security protocols agreed to by FNS and a State agency administering SNAP, each State agency shall ensure that FNS has complete access, including remote access for QC purposes, to both the records that are used in the administration of SNAP, including but not limited to the records contained within certification and EBT systems, and the information systems in which such records are contained.

■ 3. In § 275.3:

■ a. Redesignate paragraphs (c) and (d) as paragraphs (d) and (e); and

■ b. Add a new paragraph (c).

The addition reads as follows:

§ 275.3 Federal Monitoring.

* * * * *

(c) *Reviews of State Agency's Quality Control System.* FNS will conduct a management evaluation (ME) of at least two State Quality Control systems annually, to the maximum extent practicable. The ME will include, but not be limited to, a determination of whether the State agency is complying with FNS regulations; an assessment of the State agency's methods and procedures for conducting and managing the Quality Control system; and an assessment of the data collected by the State agency and submitted to the FNS Regional Office for conducting reviews.

* * * * *

■ 4. Amend § 275.4 by revising paragraph (c) to read as follows:

§ 275.4 Record retention.

* * * * *

(c) QC review records consist of Forms FNS–380, Worksheet for Supplemental Nutrition Assistance Program, FNS–380–1, Quality Control Review Schedule, FNS–245, Negative Quality Control Review Schedule; other materials supporting the review decision, including all correspondence with the household and all case notes, digital or otherwise, taken or used by the eligibility worker that are applicable to the review period; sample lists; sampling frames; tabulation sheets; and reports of the results of all quality control reviews during each review period.

■ 5. In § 275.11 amend paragraph (g) by:

■ a. Revising the paragraph heading;

■ b. In the first sentence, removing the phrase, '', and households participating based upon an application processed by Social Security Administration personnel'';

■ c. In the third sentence, removing the term ''§ 275.21(e)'' and adding, in its place, the term ''§ 275.21(d)'';

■ d. In the third sentence removing the term ''§ 275.23(b)(2)'' and adding, in its place, the term ''§ 275.23(b)(1)''; and

■ e. Removing the sixth and seventh sentences.

The revision reads as follows:

§ 275.11 Sampling.

* * * * *

(g) *Demonstration projects.* * * *

■ 6. In § 275.12 amend paragraph (h) by:

■ a. Revising the paragraph heading; and

■ b. Removing the third and fourth sentences.

The revision reads as follows:

§ 275.12 Review of active cases.

* * * * *

(h) *Demonstration projects.* * * *

■ 7. In § 275.13 amend paragraph (f) by:

■ a. Revising the paragraph heading; and

■ b. Removing the last sentence.

The revision reads as follows:

§ 275.13 Review of negative cases.

* * * * *

(f) *Demonstration projects.* * * *

■ 8. In § 275.21:

■ a. Revise paragraph (b); and

■ b. In paragraph (d):

■ i. Revise the paragraph heading; and

■ ii. Removing the phrase ''/SSA processed cases'' from the first sentence.

The revisions read as follows:

§ 275.21 Quality control review reports.

* * * * *

(b) *Individual cases.* The State agency shall report the review findings on each case selected for review during the sample month. For active cases, the State agency shall thoroughly document the Quality Control Review Schedule, Form FNS–380, to ensure any subsequent case reviewers fully understand household circumstances pertaining to the QC review as well as the reasons for the individual case finding and disposition. The State agency shall also code the findings on the Form FNS–380–1. For negative cases, the State agency shall submit a summary report, coded and documented on the Negative Quality Control Review Schedule, Form FNS–245, in enough detail to ensure subsequent case reviewers fully understand the reasons for the individual finding and disposition. The review findings shall be reported as follows:

* * * * *

(d) *Demonstration projects.* * * *

■ 9. In § 275.23 amend paragraph (b)(1) by:

■ a. Revising the paragraph heading; and

■ b. Removing the second and third sentences of the paragraph.

The revision reads as follows:

§ 275.23 Determination of State agency program performance.

* * * * *

(b) * * *

(1) Demonstration projects. * * *

* * * * *

Stacy Dean,

Deputy Under Secretary, Food, Nutrition and Consumer Services.

[FR Doc. 2021–17254 Filed 8–12–21; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 985

[Doc. No. AMS–SC–20–0087; SC21–985–1 FR]

Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Salable Quantities and Allotment Percentages for the 2021–2022 Marketing Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Far West Spearmint Oil Administrative Committee to establish salable quantities and allotment percentages for Class 1 (Scotch) and Class 3 (Native) spearmint oil produced in Washington, Idaho, Oregon, and designated parts of Nevada and Utah (the Far West) for the 2021–2022 marketing year.

DATES: Effective September 13, 2021.

FOR FURTHER INFORMATION CONTACT: Joshua R. Wilde, Marketing Specialist, or Gary Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, or Email: *Joshua.R.Wilde@usda.gov* or *GaryD.Olson@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@usda.gov*.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Order No. 985, as amended (7 CFR part 985), regulating the handling of spearmint oil produced in the Far West. Part 985 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Far West Spearmint Oil Administrative Committee (Committee) locally administers the Order and is comprised of spearmint oil producers operating within the area of production, and a public member.

The Department of Agriculture (USDA) is issuing this final rule in conformance with Executive Orders 12866 and 13563. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This final rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. AMS has determined this final rule is unlikely to have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. Under the Order now in effect, salable quantities and allotment percentages may be established for classes of spearmint oil produced in the Far West. This rule establishes quantities and allotment percentages for Scotch and Native spearmint oil for the 2021–2022 marketing year, which begins on June 1, 2021.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to a marketing order may file with USDA a petition stating that the marketing order, any provision of the marketing order, or any obligation imposed in connection with the marketing order is not in accordance with law and request a modification of the marketing order or to be exempted therefrom. Such a handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed

no later than 20 days after the date of the entry of the ruling.

Pursuant to §§ 985.50, 985.51, and 985.52, the Order requires the Committee to meet each year to consider supply and demand of spearmint oil and to adopt a marketing policy for the ensuing marketing year. When such considerations indicate a need to establish or to maintain stable market conditions through volume regulation, the Committee recommends salable quantity limitations and producer allotments to regulate the quantity of Far West spearmint oil available to the market.

According to § 985.12, ''salable quantity'' is the total quantity of each class of oil (Scotch or Native) that handlers may purchase from, or handle on behalf of, producers during a given marketing year. The total industry allotment base is the aggregate of all allotment bases held individually by producers as prescribed under § 985.53(d)(1). The total allotment base is revised each year on June 1 to account for producer base being lost as a result of the ''bona fide effort'' production provision of § 985.53(e) and additional base made available pursuant to the provisions of § 985.153.

Each producer's prorated share of the salable quantity of each class of oil, or the ''annual allotment'' as defined in § 985.13, is calculated by using an allotment percentage. The allotment percentage is derived by dividing the salable quantity of each class of spearmint oil by the total industry allotment base for that same class of oil.

The Committee met on October 14, 2020, to consider its marketing policy for the 2021–2022 marketing year. At that meeting, the Committee determined that, based on the current market and supply conditions, volume regulation for both classes of oil would be necessary. With a 6–1 vote, the Committee recommended a salable quantity and allotment percentage for Scotch spearmint oil of 846,684 pounds and 38 percent. The member voting in opposition to the recommendation favored volume regulation but supported an unspecified lower salable quantity and allotment percent than what was recommended. The Committee voted six in favor, with one abstention, to recommend a salable quantity and allotment percentage for Native spearmint oil of 938,397 pounds and 37 percent. The member abstaining did not give a reason.

This action establishes the amount of Scotch and Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2021–2022 marketing year, which begins on June 1, 2021. Salable quantities and allotment percentages have been placed into effect each season since the Order's inception in 1980.

Scotch Spearmint Oil

The Committee recommended a Scotch spearmint oil salable quantity of 846,684 pounds and an allotment percentage of 38 percent for the 2021–2022 marketing year. The 2021–2022 marketing year salable quantity of 846,684 pounds is 8,355 pounds more than the 2020–2021 marketing year salable quantity of 838,329 pounds. The allotment percentage, recommended at 38 percent for the 2021–2022 marketing year, is the same as the percentage in effect the previous year. The total allotment base for the coming marketing year is estimated to be 2,228,116 pounds. This figure represents a one-percent increase over the 2020–2021 marketing year total allotment base of 2,206,055 pounds. The salable quantity (846,684 pounds) is the product of total allotment base (2,228,116 pounds) times the allotment percentage (38 percent).

The Committee considered several factors in making its recommendation, including the current and projected future supply, estimated future demand, production costs, and producer prices. The Committee's recommendation also accounts for the established acreage of Scotch spearmint, consumer demand, existing carry-in, reserve pool volume, and increased production in competing markets.

According to the Committee, as costs of production have increased and spearmint oil prices have decreased, many producers have forgone new plantings of Scotch spearmint. This has resulted in a significant decline in production of Scotch spearmint oil in recent years. Production has decreased from 1,113,346 pounds produced in 2016 to an estimated 498,322 pounds of Scotch spearmint oil produced in 2020.

Industry reports indicate that trade demand for Far West Scotch spearmint oil has decreased over the past five years as international markets for spearmint-flavored products have slowed. Sales of Far West Scotch spearmint oil have averaged 740,216 pounds per year over the last five years but have averaged only 645,965 pounds over the last three years. In addition to declining spearmint oil demand, increasing production of Scotch spearmint oil in competing markets, most notably by Canadian producers, has put additional downward pressure on the Far West Scotch spearmint oil market.

Given the general decline in demand and anticipated market conditions for the coming year, the Committee estimates that Scotch spearmint oil trade demand for the 2021–2022 marketing year trade will be 623,000 pounds, which is 19,000 pounds higher than the prior year estimate, but still down from the three-year average of actual sales. Should the volume regulation levels established by this action prove insufficient to adequately supply the market, the Committee has the authority to recommend intra-seasonal increases, as it has in previous marketing years.

The Committee calculated the minimum salable quantity of Scotch spearmint oil that will be required during the 2021–2022 marketing year (359,424 pounds) by subtracting the estimated salable carry-in on June 1, 2021, (263,576 pounds) from the estimated trade demand (623,000 pounds). This minimum salable quantity represents the estimated minimum amount of Scotch spearmint oil that will be needed to satisfy estimated trade demand for the coming year. To ensure that the market will be fully supplied, the Committee recommended a 2021–2022 marketing year salable quantity of 846,684 pounds. The recommended salable quantity, combined with an estimated 263,576 pounds of salable quantity carried in from the previous year, will yield a total available supply of 1,110,260 pounds of Scotch spearmint oil for the 2021–2022 marketing year. With the recommended salable quantity and current market environment, the Committee estimates that as much as 487,260 pounds of salable Scotch spearmint oil could be carried into the 2022–2023 marketing year.

Salable carry-in is the primary measure of excess spearmint oil supply under the Order, as it represents overproduction in prior years that is currently available to the market without restriction. Under volume regulation, spearmint oil that is designated as salable continues to be available to the market until it is sold and may be marketed at any time at the discretion of the owner. Salable quantities established under volume regulation over the last four seasons have exceeded sales, leading to a gradual build of Scotch spearmint oil salable carry-in.

The Committee estimates that there will be 263,576 pounds of salable carry-in of Scotch spearmint oil on June 1, 2021. If current market conditions are maintained and the Committee's projections are correct, salable carry-in will increase to 487,260 pounds at the beginning of the 2022–2023 marketing year. This level will be above the

quantity that the Committee generally considers favorable (150,000 pounds). However, the Committee believes that, given the current economic conditions in the Scotch spearmint oil industry, some Scotch spearmint oil producers may not produce enough oil in the 2021–2022 marketing year to fill all of their annual allotment. The Committee estimates that as much as 245,352 pounds of 2020–2021 marketing year annual allotment may not be filled by producers. While the Committee has not projected unused base allotment for the 2021–2022 marketing year and did not incorporate this factor in its recommendation, it anticipates that the actual quantity of Scotch spearmint oil carried into the following marketing year will be significantly less than the quantity calculated above (487,260 pounds).

Spearmint oil held in reserve is oil that has been produced in excess of a producer's marketing year allotment and is not available to the market in the current marketing year without an increase in the salable quantity and allotment percentage. Oil held in the reserve pool is another indicator of excess supply. Scotch spearmint oil held in the reserve pool was 67,645 pounds as of May 31, 2020, down from 132,984 pounds as of May 31, 2019. However, the Scotch spearmint oil reserve is expected to rebound slightly to an estimated 83,608 pounds by the end of the 2020–2021 marketing year. This quantity of reserve pool oil should be an adequate buffer to supply the market, if necessary, should the industry experience an unexpected increase in demand.

The Committee recommended an allotment percentage of 38 percent for the 2021–2022 marketing year for Scotch spearmint oil. During its October 14, 2020, meeting, the Committee calculated an initial allotment percentage by dividing the minimum required salable quantity (359,424 pounds) by the total estimated allotment base (2,228,116 pounds), resulting in 16.1 percent. However, producers and handlers at the meeting indicated that the computed percentage (16.1 percent) might not adequately supply potential 2021–2022 Scotch spearmint oil market demand and may also result in a less than desirable carry-in for the subsequent marketing year. After deliberation, the Committee increased the recommended allotment percentage to 38 percent. The total estimated allotment base (2,228,116 pounds) for the 2021–2022 marketing year, multiplied by the recommended salable allotment percentage (38 percent), yields 846,684 pounds, which is the recommended salable quantity for the 2021–2022 marketing year.

The 2021–2022 marketing year computational data for the Committee's recommendations is detailed below.

(A) *Estimated carry-in of Scotch spearmint oil on June 1, 2021: 263,576 pounds.* This figure is the difference between the 2020–2021 marketing year total available supply of 867,576 pounds and the 2020–2021 marketing year estimated trade demand of 604,000 pounds. The estimated 2020–2021 marketing year trade demand was revised down from the original estimate of 750,000 pounds by the Committee at its October 14, 2020, meeting.

(B) *Estimated trade demand of Scotch spearmint oil for the 2021–2022 marketing year: 623,000 pounds.* This figure was established at the Committee meeting held on October 14, 2020.

(C) *Salable quantity of Scotch spearmint oil required from the 2021–2022 marketing year production: 359,424 pounds.* This figure is the difference between the estimated 2021–2022 marketing year trade demand (623,000 pounds) and the estimated carry-in on June 1, 2021 (263,576 pounds). This salable quantity represents the minimum amount of Scotch spearmint oil that may be needed to satisfy estimated demand for the coming year.

(D) *Total estimated Scotch spearmint oil allotment base for the 2021–2022 marketing year: 2,228,116 pounds.* This figure represents a one-percent increase over the 2020–2021 total actual allotment base of 2,206,055 pounds, as prescribed by § 985.153. The one-percent increase equals 22,061 pounds. This total estimated allotment base is revised each year on June 1 in accordance with § 985.53(e).

(E) *Computed Scotch spearmint oil allotment percentage for the 2021–2022 marketing year: 16.1 percent.* This percentage is computed by dividing the minimum required salable quantity (359,424 pounds) by the total estimated allotment base (2,228,116 pounds).

(F) *Recommended Scotch spearmint oil allotment percentage for the 2021–2022 marketing year: 38 percent.* This is the Committee's recommendation and is based on the computed allotment percentage (16.1 percent) and input from producers and handlers at the October 14, 2020, meeting. The recommended 38 percent allotment percentage reflects the Committee's belief that the computed percentage (16.1 percent) may not adequately supply the anticipated 2021–2022 marketing year Scotch spearmint oil market demand.

(G) *Recommended Scotch spearmint oil salable quantity for the 2021–2022 marketing year: 846,684 pounds.* This figure is the product of the recommended salable allotment percentage (38 percent) and the total estimated allotment base (2,228,116 pounds) for the 2021–2022 marketing year.

(H) *Estimated total available supply of Scotch spearmint oil for the 2021–2022 marketing year: 1,110,260 pounds.* This figure is the sum of the 2021–2022 marketing year recommended salable quantity (846,684 pounds) and the estimated carry-in on June 1, 2021 (263,576 pounds).

For the reasons stated above, the Committee believes that the recommended salable quantity and allotment percentage will adequately satisfy trade demand, will result in a reasonable carry-in for the following year, and will contribute to the orderly marketing of Scotch spearmint oil.

Native Spearmint Oil

The Committee recommended a Native spearmint oil salable quantity of 938,397 pounds and an allotment percentage of 37 percent for the 2021–2022 marketing year. These figures are, respectively, 292,089 pounds and 12 percentage points lower than the levels established for the 2020–2021 marketing year. The Committee utilized handlers' estimated trade demand of Native spearmint oil for the coming year, historical and current Native spearmint oil production, inventory statistics, and international market data obtained from consultants for the spearmint oil industry to arrive at these recommendations.

The Committee anticipates that 2021 Native spearmint oil production will total 1,181,230 pounds, down substantially from the previous year's production of 1,493,686 pounds. Committee records show an estimated 7,957 acres of Native spearmint production in the Far West in 2020 compared to an estimated 9,013 acres of Native spearmint production in 2019.

Sales of Native spearmint oil have also been declining, falling from a high of 1,565,515 pounds in the 2017–2018 marketing year to 1,076,906 pounds over the 2019–2020 marketing year, the last full year of reported sales. The Committee estimates that trade demand for Native spearmint oil will be 1,059,167 pounds for the 2020–2021 marketing year, well below the 5-year sales average of 1,283,266 pounds.

The Committee expects that 694,137 pounds of salable Native spearmint oil from prior years will be carried into the 2021–2022 marketing year. This amount

is up from the 522,818 pounds of salable oil carried into the 2020–2021 marketing year and well above the level that the Committee generally considers favorable.

Further, the Committee estimates that there will be 1,130,264 pounds of Native spearmint oil in the reserve pool at the beginning of the 2021–2022 marketing year. This figure is 49,256 pounds lower than the quantity of reserve pool oil held by producers on June 1, 2020, but is still higher than the level that the Committee believes is optimal. This modest decline in the reserve oil reverses the recent trend of gradual increases that the industry has experienced over the past several marketing years.

The Committee expects end users of Native spearmint oil to continue to rely on Far West production as their primary source of high-quality Native spearmint oil. Overseas production of Native spearmint has declined in recent years. As a result, U.S. exports of Native spearmint oil have been increasing since 2018. However, the increase in domestic production from other states outside the Far West region has more than offset the decline in foreign production of Native spearmint oil. For instance, production of Native spearmint oil in the U.S. Midwest region has spiked in recent years, rising from fewer than 2,000 acres in 2016 to approximately 5,500 acres in 2020. Additionally, the sharp increase in demand for Native spearmint experienced during the 2017–2018 marketing year has tapered off in recent years. These factors have contributed to declining trade demand for Far West Native spearmint oil and led to downward pressure on producer prices.

The Committee chose to be cautiously optimistic in the establishment of its trade demand estimate for the 2021–2022 marketing year to ensure that the market will be adequately supplied. At the October 14, 2020, meeting, the Committee estimated the 2021–2022 marketing year Native spearmint oil trade demand to be 1,125,000 pounds. This figure is based on input provided by producers at nine production area meetings held in early October 2020, as well as estimates provided by handlers and other meeting participants. This figure represents an increase of 65,833 pounds from the previous year's revised trade demand estimate. The average estimated trade demand for Native spearmint oil derived from the area producer meetings was 1,105,556 pounds, whereas the handlers' estimates ranged from 900,000 to 1,300,000 pounds. The average of Native spearmint oil sales over the last three years was 1,295,832 pounds. The quantity marketed over the most recent full marketing year, 2019–2020, was 1,076,906 pounds.

The estimated June 1, 2021, carry-in of 694,137 pounds of Native spearmint oil, plus the recommended 2021–2022 marketing year salable quantity of 938,397 pounds, results in an estimated total available supply of 1,632,534 pounds of Native spearmint oil during the 2021–2022 marketing year. With the corresponding estimated trade demand of 1,125,000 pounds, the Committee projects that 507,534 pounds of oil will be carried into the 2022–2023 marketing year, resulting in a year-over-year decrease of 186,603 pounds. The Committee estimates that there will be 1,130,264 pounds of Native spearmint oil held in the reserve pool at the beginning of the 2021–2022 marketing year. Should the industry experience an unexpected increase in trade demand, oil in the Native spearmint oil reserve pool could be released through an intra-seasonal increase to satisfy that demand.

The Committee recommended a producer allotment percentage of 37 percent for the 2021–2022 marketing year. During its October 14, 2020, meeting, the Committee calculated an initial producer allotment percentage of 17 percent by dividing the minimum required salable quantity to satisfy estimated trade demand (430,863 pounds) by the total allotment base (2,536,208 pounds). However, producers and handlers at the meeting expressed that the computed percentage of 17 percent may not adequately supply the potential 2021–2022 Native spearmint oil market demand or result in adequate carry-in for the subsequent marketing year. After deliberation, the Committee increased the recommended allotment percentage to 37 percent. The total estimated allotment base (2,536,208 pounds) for the 2021–2022 marketing year multiplied by the recommended salable allotment percentage (37 percent) yields 938,397 pounds, the recommended salable quantity for the year.

The 2021–2022 marketing year computational data for the Committee's recommendations is further outlined below.

(A) *Estimated carry-in of Native spearmint oil on June 1, 2021: 694,137 pounds.* This figure is the difference between the revised 2020–2021 marketing year total available supply of 1,753,304 pounds and the revised 2020–2021 marketing year estimated trade demand of 1,059,167 pounds.

(B) *Estimated trade demand of Native spearmint oil for the 2021–2022 marketing year: 1,125,000 pounds.* This estimate was established by the Committee at the October 14, 2020, meeting.

(C) *Salable quantity of Native spearmint oil required from the 2021–2022 marketing year production: 430,863 pounds.* This figure is the difference between the estimated 2021–2022 marketing year estimated trade demand (1,125,000 pounds) and the estimated carry-in on June 1, 2021 (694,137 pounds). This is the minimum amount of Native spearmint oil that the Committee believes will be required to meet the anticipated 2021–2022 marketing year trade demand.

(D) *Total estimated allotment base of Native spearmint oil for the 2021–2022 marketing year: 2,536,208 pounds.* This figure represents a one-percent increase over the 2020–2021 total actual allotment base of 2,511,097 pounds as prescribed in § 985.153. The one-percent increase equals 25,111 pounds of oil. This estimate is revised each year on June 1, due to adjustments resulting from the bona fide effort production provisions of § 985.53(e).

(E) *Computed Native spearmint oil allotment percentage for the 2021–2022 marketing year: 17 percent.* This percentage is calculated by dividing the required salable quantity (430,863 pounds) by the total estimated allotment base (2,536,208 pounds) for the 2021–2022 marketing year.

(F) *Recommended Native spearmint oil allotment percentage for the 2021–2022 marketing year: 37 percent.* This is the Committee's recommendation based on the computed allotment percentage (17 percent) and input from producers and handlers at the October 14, 2020, meeting. The recommended 37 percent allotment percentage is also based on the Committee's belief that the computed percentage (17 percent) may not adequately supply the potential market for Native spearmint oil in the 2021–2022 marketing year or allow for salable Native spearmint oil to be carried into the beginning of the 2022–2023 marketing year.

(G) *Recommended Native spearmint oil 2021–2022 marketing year salable quantity: 938,397 pounds.* This figure is the product of the recommended allotment percentage (37 percent) and the total estimated allotment base (2,536,208 pounds).

(H) *Estimated available supply of Native spearmint oil for the 2021–2022 marketing year: 1,632,534 pounds.* This figure is the sum of the 2021–2022 recommended salable quantity (938,397 pounds) and the estimated carry-in on June 1, 2021 (694,137 pounds). This amount could be increased, as needed, through an intra-seasonal increase in the

salable quantity and allotment percentage.

The Committee's recommended Scotch and Native spearmint oil salable quantities and allotment percentages of 846,684 pounds and 38 percent, and 938,397 pounds and 37 percent, respectively, will match the available supply of each class of spearmint oil to the estimated demand of each, thus avoiding extreme fluctuations in inventories and prices. This rule is similar to regulations issued in prior seasons.

The salable quantities established in this final rule are not expected to cause a shortage of either class of spearmint oil. Any unanticipated or additional market demand for either class of spearmint oil which may develop during the marketing year could be satisfied by an intra-seasonal increase in the salable quantity and corresponding allotment percentage. The Order contains a provision in § 985.51 for intra-seasonal increases to allow the Committee the flexibility to respond quickly to changing market conditions.

Under volume regulation, producers who produce more than their annual allotments during the marketing year may transfer such excess spearmint oil to producers who have produced less than their annual allotment. In addition, on December 1 of each year, producers who have not transferred their excess spearmint oil to other producers must place their excess spearmint oil production into the reserve pool to be released in the future, in accordance with market needs and under the Committee's direction.

USDA has reviewed the Committee's marketing policy statement for the 2021–2022 marketing year. The Committee's marketing policy statement, a requirement whenever the Committee recommends volume regulation, meets the requirements of §§ 985.50 and 985.51.

The establishment of salable quantities and allotment percentages in this rule is expected to fully satisfy anticipated market needs. In determining anticipated market needs, the Committee considered historical sales, as well as changes and trends in production and demand. This rule also provides producers with information regarding the amount of spearmint oil that should be produced for the 2021–2022 season to meet anticipated market demand.

Final Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 40 producers and 94 producers of Scotch and Native spearmint oil, respectively, in the regulated production area and approximately 8 spearmint oil handlers subject to regulation under the Order. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of less than $30,000,000, and small agricultural producers are defined as those having annual receipts of less than $1,000,000 (13 CFR 121.201).

The Committee reported that recent producer prices for spearmint oil have ranged from $12.00 to $17.00 per pound. The National Agricultural Statistics Service (NASS) reported that the 2019 U.S. season average spearmint oil producer price per pound was $16.90. Spearmint oil utilization for the 2019–2020 marketing year, as reported by the Committee, was 598,706 pounds and 1,076,906 pounds for Scotch and Native spearmint oil, respectively, for a total of 1,675,612 pounds. Multiplying $16.90 per pound by 2019–2020 marketing year spearmint oil utilization of 1,675,612 pounds yields a crop value estimate of about $28.3 million.

Given the accounting requirements for the volume regulation provisions of the Order, the Committee maintains accurate records of each producer's production and sales. Using the $16.90 average spearmint oil price, and Committee production data for each producer, the Committee estimates that 37 of the 40 Scotch spearmint oil producers and 90 of the 94 Native spearmint oil producers could be classified as small entities under the SBA definition.

There is no third party or governmental entity that collects and reports spearmint oil prices received by spearmint oil handlers. However, the Committee estimates an average spearmint oil handling markup at approximately 20 percent of the price received by producers. Multiplying 1.20 by the 2018 producer price of $16.90 yields a handler free on board (f.o.b.) price per pound estimate of $20.28.

Multiplying this estimated handler f.o.b. price by the 2019–2020 marketing year total spearmint oil utilization of 1,675,612 pounds results in an estimated handler-level spearmint oil value of $33.98 million. Dividing this figure by the number of handlers (8) yields estimated average annual handler receipts of about $4.25 million, which is well below the SBA threshold for small agricultural service firms.

Furthermore, using confidential data on pounds handled by each handler, and the abovementioned estimated handler price per pound, the Committee reported that it is not likely that any of the eight handlers had 2019–2020 marketing year spearmint oil sales that exceeded the $30 million SBA threshold.

Therefore, the majority of producers of spearmint oil may be classified as small entities, and all of the handlers of spearmint oil may be classified as small entities.

This final rule establishes the quantity of spearmint oil produced in the Far West, by class, which handlers may purchase from, or handle on behalf of, producers during the 2021–2022 marketing year. The Committee recommended this action to help maintain stability in the spearmint oil market by matching supply to estimated demand, thereby avoiding extreme fluctuations in supplies and prices. Establishing quantities that may be purchased or handled during the marketing year through volume regulation allows producers to coordinate their spearmint oil production with the expected market demand. Authority for this action is provided in §§ 985.50, 985.51, and 985.52 of the Order.

The Committee estimates the total trade demand for the 2021–2022 marketing year for both classes of oil at 1,748,000 pounds. In addition, the Committee expects that the combined salable carry-in for both classes of spearmint oil will be 957,713 pounds. As such, the combined required salable quantity for the 2021–2022 marketing year is estimated to be 790,287 pounds (1,748,000 pounds trade demand less 957,713 pounds carry-in). Under volume regulation, total sales of spearmint oil by producers for the 2021–2022 marketing year will be held to 2,742,794 pounds (the recommended salable quantity for both classes of spearmint oil of 1,785,081 pounds plus 957,713 pounds of carry-in).

This total available supply of 2,742,794 pounds should be more than adequate to supply the 1,748,000

pounds of anticipated total trade demand for spearmint oil. In addition, as of May 31, 2020, the total reserve pool for both classes of spearmint oil stood at 1,247,165 pounds. That quantity is expected to remain relatively unchanged over the course of the 2021–2022 marketing year, with current Committee reserve pool estimates totaling 1,366,673 pounds. Should trade demand increase unexpectedly during the 2021–2022 marketing year, reserve pool spearmint oil could be released into the market to supply that increase in demand.

The established allotment percentages, upon which 2021–2022 marketing year annual allotments are based, are 38 percent for Scotch spearmint oil and 37 percent for Native spearmint oil. Without volume regulation, producers will not be held to these allotment levels, and could sell unrestricted quantities of spearmint oil.

The USDA econometric model used to evaluate the Far West spearmint oil market estimated that the season average producer price per pound (from both classes of spearmint oil) would decline about $1.70 per pound without volume regulation. The surplus situation for the spearmint oil market that would exist without volume regulation in the 2021–2022 marketing year also would likely dampen prospects for improved producer prices in future years because of the excessive buildup in stocks.

In addition, the econometric model estimated that spearmint oil prices would fluctuate with greater amplitude in the absence of volume regulation. The coefficient of variation, or CV (a standard measure of variability), of Far West spearmint oil producer prices for the period 1980–2019 (the years in which the Order has been in effect), is 25 percent, compared to 49 percent for the 20-year period (1960–1979) immediately prior to the establishment of the Order. Since higher CV values correspond to greater variability, this is an indicator of the price stabilizing impact of the Order.

The use of volume regulation allows the industry to fully supply spearmint oil markets while avoiding the negative consequences of over-supplying these markets. The use of volume regulation is believed to have little or no effect on consumer prices of products containing spearmint oil and will not result in fewer retail sales of such products.

The Committee discussed alternatives to the recommendations contained in this rule for both classes of spearmint oil. The Committee rejected the idea of not regulating volume for either class of spearmint oil because of the severe, price-depressing effects that will likely occur without volume regulation. The Committee also discussed and considered salable quantities and allotment percentages that were above and below the levels that were ultimately recommended for both classes of spearmint oil. Ultimately, the action recommended by the Committee was to maintain the allotment percentage for Scotch spearmint oil (which will slightly increase the salable quantity) and to decrease both the salable quantity and allotment percentage for Native spearmint oil from the levels established for the 2020–2021 marketing year.

As noted earlier, the Committee's recommendation to establish salable quantities and allotment percentages for both classes of spearmint oil was made after careful consideration of all available information including: (1) The estimated quantity of salable oil of each class held by producers and handlers; (2) the estimated demand for each class of oil; (3) the prospective production of each class of oil; (4) the total of allotment bases of each class of oil for the current marketing year and the estimated total of allotment bases of each class for the ensuing marketing year; (5) the quantity of reserve oil, by class, in storage; (6) producer prices of oil, including prices for each class of oil; and (7) general market conditions for each class of oil, including whether the estimated season average price to producers is likely to exceed parity.

Based on its review, the Committee believes that the salable quantities and allotment percentages established in this rule will achieve the objectives sought. The Committee also believes that, should there be no volume regulation in effect for the upcoming marketing year, the Far West spearmint oil industry will return to the pronounced cyclical price patterns that occurred prior to the promulgation of the Order. As previously stated, annual salable quantities and allotment percentages have been issued for both classes of spearmint oil since the Order's inception. The salable quantities and allotment percentages established herein are expected to facilitate the goal of maintaining orderly marketing conditions for Far West spearmint oil for the 2021–2022 and future marketing years.

Costs to producers and handlers, large and small, resulting from this action are expected to be offset by the benefits derived from a more stable market and increased returns. The benefits of this rule are expected to be equally available to all producers and handlers regardless of their sizes.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, Vegetable and Specialty Crops. No changes in those requirements are necessary as a result of this rule. Should any changes become necessary, they would be submitted to OMB for approval.

This rule establishes the salable quantities and allotment percentages for Scotch spearmint oil and Native spearmint oil produced in the Far West during the 2021–2022 marketing year. Accordingly, this rule does not impose any additional reporting or recordkeeping requirements on either small or large spearmint oil producers or handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

A proposed rule concerning this action was published in the **Federal Register** on April 16, 2021 (86 FR 20038). Copies of the proposed rule were also mailed or sent via email to all Far West spearmint oil handlers. The proposal was made available through the internet by USDA and the Office of the Federal Register. A 60-day comment period ending June 15, 2021, was provided for interested persons to respond to the proposal. No comments were received during the comment period. Accordingly, no changes will be made to the rule as proposed.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Board and other available information, it is hereby found that this rule will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 985

Marketing agreements, Oils and fats, Reporting and recordkeeping requirements, Spearmint oil.

For the reasons set forth in the preamble, 7 CFR part 985 is amended as follows:

PART 985—MARKETING ORDER REGULATING THE HANDLING OF SPEARMINT OIL PRODUCED IN THE FAR WEST

■ 1. The authority citation for 7 CFR part 985 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 985.236 is added to read as follows:

§ 985.236 Salable quantities and allotment percentages—2021–2022 marketing year.

The salable quantity and allotment percentage for each class of spearmint oil during the marketing year beginning on June 1, 2021, shall be as follows:

(a) Class 1 (Scotch) oil—a salable quantity of 846,684 pounds and an allotment percentage of 38 percent.

(b) Class 3 (Native) oil—a salable quantity of 938,397 pounds and an allotment percentage of 37 percent.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–17293 Filed 8–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 212, 214, 245 and 274a

[CIS No. 2507–11; DHS Docket No USCIS–2011–0010]

RIN 1615–AA59

Classification for Victims of Severe; Forms of Trafficking in Persons; Eligibility for ''T'' Nonimmigrant Status; Extension of Comment Period

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Interim final rule; extension of the comment period.

SUMMARY: On July 16, 2021, the Department of Homeland Security (DHS) reopened the public comment period for the interim final rule titled ''Classification for Victims of Severe Forms of Trafficking in Persons; Eligibility for ''T'' Nonimmigrant Status,'' with a comment period ending August 16, 2021. DHS is announcing that the reopened comment period will be extended an additional 30 days. As part of this rulemaking, DHS will consider comments received during the entire public comment period, including comments received since July 16, 2021.

DATES: The comment period for the interim final rule published at 81 FR 92266 (Dec. 19, 2016), which was reopened on July 16, 2021, at 86 FR 37670, is extended. Written comments and related material must be submitted on or before September 14, 2021.

ADDRESSES: You may submit comments on the entirety of this rule package, to include the related information collection requirements set forth in the 2016 interim final rule (IFR), which is identified as DHS Docket No. USCIS–2011–0010, through the *Federal eRulemaking Portal http://www.regulations.gov.* Follow the website instructions for submitting comments. Comments submitted in another manner, including emails or letters sent to DHS or U.S. Citizenship and Immigration Services (USCIS) officials, will not be considered comments on the rule and may not receive a response from DHS. Please note that DHS and USCIS cannot accept any comments that are hand delivered or couriered. In addition, USCIS cannot accept comments contained on any form of digital media storage devices, such as CDs/DVDs and USB drives. Due to COVID–19, USCIS is also not accepting mailed comments at this time. If you cannot submit your comment by using *http://www.regulations.gov,* please contact Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, by telephone at 240–721–3000 for alternate instructions.

FOR FURTHER INFORMATION CONTACT: Andria Strano, Acting Branch Chief, Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, DHS, 5900 Capital Gateway Drive, Camp Springs, MD 20746; telephone 240–721–3000 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone numbers above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this rule. DHS also invites comments that relate to the economic or federalism effects that might result from this rule. Comments that will provide the most assistance to DHS will reference a specific portion of the rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change.

Instructions: All submissions received must include the agency name and DHS Docket No. USCIS–20011–0010. Providing comments is entirely voluntary. Regardless of how comments are submitted to DHS, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov* and will include any personal information provided by commenters. Because the information submitted will be publicly available, commenters should consider limiting the amount of personal information provided in each submission. DHS may withhold information provided in comments from public viewing if it determines that such information is offensive or may affect the privacy of an individual. For additional information, please read the Privacy Act notice available through the link in the footer of *http://www.regulations.gov.*

Docket: For access to the docket, go to *http://www.regulations.gov* and enter this rulemaking's eDocket number USCIS 2011–0010.

Background

On December 19, 2016, DHS published an interim final rule (IFR) in the **Federal Register** at 81 FR 92266 and received 17 public comments. In this IFR, USCIS amended its regulations governing the classification for Victims of Severe Forms of Trafficking in Persons; Eligibility for T Nonimmigrant Status, *see* Immigration and Nationality Act (INA) sec. 101(a)(15)(T), 8 U.S.C. 1101(a)(15)(T). On July 16, 2021, at 86 FR 37670, DHS published a document reopening the comment period for this rulemaking for 30 days, with the deadline to submit comments set at August 16, 2021. DHS has received a request from multiple stakeholders to extend the deadline for submitting public comments during the reopened public comment period. In response to that request, DHS is extending the reopened comment period for an additional 30 days, to provide a total of 60 days for the public to submit comments. Through this document, DHS is extending the comment period for the IFR published in the **Federal Register** at 86 FR 37670 until September 14, 2021. DHS will consider comments received during the entire public

comment period, including comments received since July 16, 2021.

Ur M. Jaddou,

Director, U.S. Citizenship and Immigration Services.

[FR Doc. 2021–17510 Filed 8–12–21; 8:45 am]

BILLING CODE 9111–97–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 15, 170, and 171

[NRC–2018–0292]

RIN 3150–AK24

Revision of Fee Schedules; Fee Recovery for Fiscal Year 2021

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; delay of effective date.

SUMMARY: On June 16, 2021, the U.S. Nuclear Regulatory Commission (NRC) published a final rule that amends its regulations pertaining to user fees and annual fees charged to its applicants and licensees. These amendments are necessary to implement the Nuclear Energy Innovation and Modernization Act, which, beginning with fiscal year 2021, requires the NRC to recover, to the maximum extent practicable, approximately 100 percent of its annual budget less certain amounts excluded from this fee recovery requirement. In addition, the final rule also included improvements associated with fee invoicing to implement provisions of NEIMA. The final rule had an original effective date of August 16, 2021. This document delays the effective date of the final rule to August 20, 2021, to ensure that the rule has the 60-day delayed effective date required by the Congressional Review Act.

DATES: As of August 13, 2021, the effective date of the rule amending 10 CFR parts 15, 170, and 171 published at 86 FR 32146, June 16, 2021, is delayed until August 20, 2021.

ADDRESSES: Please refer to Docket ID NRC–2018–0292 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0292. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov*.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jo A. Jacobs, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8388, email: *Jo.Jacobs@nrc.gov*.

SUPPLEMENTARY INFORMATION: On June 16, 2021 (86 FR 32146), the NRC published a final rule that amends the licensing, inspection, special project, and annual fees charged to its applicants and licensees. These amendments are necessary to implement the Nuclear Energy Innovation and Modernization Act (NEIMA), which, beginning with fiscal year (FY) 2021, requires the NRC to recover, to the maximum extent practicable, approximately 100 percent of its annual budget less certain amounts excluded from this fee recovery requirement. In addition, the final rule also included improvements associated with fee invoicing to implement provisions of NEIMA.

The FY 2021 final fee rule had an original effective date of August 16, 2021, which is 60 days after the date of publication in the **Federal Register**. The Congressional Review Act (CRA) requires a 60-day delay in the effective date of any rule determined to be a ''major'' rule [1] by the Office of Management and Budget (OMB). The OMB determined the FY 2021 final fee rule to be a major rule under the CRA. The 60-day delay in effective date begins with the date of publication in the **Federal Register** or the date of congressional notification, whichever is later. Publication of the FY 2021 final fee rule occurred on Wednesday, June 16, 2021, and congressional notification occurred on Thursday, June 17, 2021; however, due to the Federal observance of the Juneteenth national holiday on Friday, June 18, 2021, and the weekend, the congressional notification was not formally recorded until Monday, June 21, 2021, a delay of four days. Therefore, to ensure that the rule has the 60-day delayed effective date required by the CRA, this document delays the effective date of the FY 2021 final fee rule until August 20, 2021.

Dated: August 10, 2021.

For the Nuclear Regulatory Commission.

Cherish K. Johnson,

Chief Financial Officer.

[FR Doc. 2021–17399 Filed 8–12–21; 8:45 am]

BILLING CODE 7590–01–P

[1] Under the CRA, a ''major'' rule is defined as a rule that OMB determines has resulted in or is likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs for consumers, individual industries, Federal, State, or local government agencies, or geographical regions; or (3) a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2021–0108]

RIN 3150–AK64

List of Approved Spent Fuel Storage Casks: TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System, Certificate of Compliance No. 1029, Renewal of Initial Certificate and Amendment Nos. 1, 3, and 4

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its spent fuel storage regulations by revising the TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System listing within the ''List of approved spent fuel storage casks'' to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029. The renewal of the initial certificate and Amendment Nos. 1, 3, and 4 revises the certificate of compliance's conditions and technical specifications to address aging management activities related to the structures, systems, and components of the dry storage system to ensure that these will maintain their intended functions during the period of extended storage operations.

DATES: This direct final rule is effective October 27, 2021, unless significant adverse comments are received by

September 13, 2021. If this direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2021–0108 at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christopher Markley, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6293, email: *Christopher.Markley@nrc.gov* and Irene Wu, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–1951, email: *Irene.Wu@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0108 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0108. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2021–0108 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

This rule is limited to the renewal of the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029 and does not include other aspects of TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System. Amendment No. 2 was withdrawn and not issued by the NRC. The NRC is using the ''direct final rule procedure'' to issue this renewal because it represents a limited and routine change to an existing certificate of compliance that is expected to be non-controversial. Adequate protection of public health and safety continues to be reasonably assured. The amendment to the rule will become effective on October 27, 2021. However, if the NRC receives any significant adverse comments on this direct final rule by September 13, 2021, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis.

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule, certificate of compliance, or technical specifications.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on January 6, 2003 (68 FR 463), that approved the Standardized Advanced NUHOMS® Horizontal Modular Storage System design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1029.

IV. Discussion of Changes

On May 22, 2019, TN Americas, LLC submitted a request to the NRC to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029 for the Standardized Advanced NUHOMS® Horizontal Modular Storage System. TN Americas, LLC, supplemented its request on December 4, 2019, and July 10, 2020.

The renewals of the initial certificate and Amendment Nos. 1, 3, and 4 were conducted in accordance with the renewal provisions in § 72.240. This section of the NRC spent fuel storage regulations authorizes NRC staff to include any additional certificate conditions it deems necessary to ensure the safe operation of the cask during the certificate's renewal period. The NRC included five additional conditions to the renewal of the initial certificate of compliance and Amendment Nos. 1, 3, and 4:

- The submittal of an updated final safety analysis report (UFSAR) to address aging management activities resulting from the renewal of the certificate of compliance. This condition ensures that the UFSAR changes are made in a timely fashion to enable general licensees using the storage system during the period of extended operation to develop and implement necessary procedures.
- The requirement that general licensees initiating or using spent fuel dry storage operations with the Standardized Advanced NUHOMS® Horizontal Modular Storage System ensure that their evaluations are included in the reports required by § 72.212, ''Conditions of general license issued under § 72.210.'' These reports will include appropriate considerations for the period of extended operation, a review of the UFSAR changes resulting from the certificate of compliance renewal, and a review of the NRC Safety Evaluation Report (SER) related to the certificate of compliance renewal.
- The requirement that future amendments and revisions to this certificate of compliance include evaluations of the impacts to aging management activities to ensure that they remain adequate for any changes to the structures, systems, and components (SSCs).
- The requirement that general licensees not use the OS197, OS197H, and OS200FC transfer casks approved under Certificate of Compliance No. 1004 aged 20 years or more to perform the transfer cask functions in the Standardized Advanced NUHOMS® Horizontal Modular Storage System. This condition prohibits the use of those transfer casks aged 20 years or older because the renewal application for the Certificate of Compliance No. 1004 did not assess performance of the transfer casks after the initial 20-year period.
- The requirement that any Standardized Advanced NUHOMS® Horizontal Modular System loaded up to and including those loaded on February 5, 2023, are considered loaded during the term of the initial certificate of compliance.

The NRC made two corresponding changes to the technical specifications for the initial certificate of compliance and Amendment Nos. 1, 3, and 4:

- Added text to the Transfer Cask Section to ensure that the requirements of the applicable transfer cask aging management program under the Renewed Certificate of Compliance No. 1004 have been satisfied.
- Added a section to the initial certificate of compliance and Amendment Nos. 1, 3, and 4 on the aging management program, which includes establishing, implementing, and maintaining written procedures for each aging management program described in the UFSAR.

As documented in the preliminary SER, the NRC performed a safety evaluation of the proposed certificate of compliance renewal request. The NRC determined that this amendment does not change the cask design or fabrication requirements in the proposed certificate of compliance renewal request. The NRC determined the design of the cask would continue to maintain confinement, shielding, and criticality control in the event of each evaluated accident condition. In addition, any resulting occupational exposure of offsite dose rates from the renewal of the initial certificate of compliance and Amendment Nos. 1, 3, and 4 would remain well within the limits specified by 10 CFR part 20, ''Standards for Protection Against Radiation.'' Thus, the NRC found there will be no significant change in the types or amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents. In its SER for the renewal of the Standardized Advanced NUHOMS® Horizontal Modular Storage System, the NRC has determined that if the conditions specified in the certificate of compliance to implement these regulations are met, adequate protection of public health and safety will continue to be reasonably assured.

This direct final rule revises the Standardized Advanced NUHOMS® Horizontal Modular Storage System listing in § 72.214 by renewing for 40 more years the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029. The renewal consists of the changes previously described, as set forth in the renewed initial certificate and amendments and their revised technical specifications. The revised technical specifications are identified in the SER.

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise

impractical. In this direct final rule, the NRC revises the TN Americas, LLC Standardized Advanced NUHOMS® Horizontal Modular Storage System design listed in § 72.214, ''List of approved spent fuel storage casks.'' This action does not constitute the establishment of a standard that contains generally applicable requirements.

VI. Agreement State Compatibility

Under the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017, and published in the **Federal Register** on October 18, 2017 (82 FR 48535), this rule is classified as Compatibility Category NRC—Areas of Exclusive NRC Regulatory Authority. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR chapter I. Therefore, compatibility is not required for program elements in this category. Although an Agreement State may not adopt program elements reserved to the NRC, and the Category ''NRC'' does not confer regulatory authority on the State, the State may wish to inform its licensees of certain requirements by means consistent with the particular State's administrative procedure laws.

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

VIII. Environmental Assessment and Finding of No Significant Impact

Under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' the NRC has determined that this direct final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC has made a finding of no significant impact based on this environmental assessment.

A. The Action

The action is to amend § 72.214 to revise the Standardized Advanced NUHOMS® Horizontal Modular Storage System listing within the ''List of approved spent fuel storage casks'' to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029.

B. The Need for the Action

This direct final rule renews the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029 for the TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System design within the list of approved spent fuel storage casks to allow power reactor licensees to store spent fuel at reactor sites in casks with the approved modifications under a general license. Specifically, this rule extends the expiration date for the TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System certificate for an additional 40 years, allowing a power reactor licensee to continue using it under general license provisions in an independent spent fuel storage installation to store spent fuel in dry casks in accordance with 10 CFR part 72.

C. Environmental Impacts of the Action

On July 18,1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent fuel under a general license in cask designs approved by the NRC. The potential environmental impact of using NRC-approved storage casks was analyzed in the environmental assessment for the 1990 final rule. The environmental assessment for the renewal of the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029 tiers off of the environmental assessment for the July 18, 1990, final rule. Tiering on past environmental assessments is a standard process under the National Environmental Policy Act of 1969, as amended. As required by § 72.240, applications for renewal of a spent fuel storage certificate of compliance design are required to demonstrate that SSCs important to safety will continue to perform their intended function for the requested renewal term. As discussed in the NRC staff's SER for the renewal of the initial certificate and Amendment Nos. 1, 3, and 4, the NRC staff has approved conditions in the renewed initial certificate and Amendment Nos. 1, 3, and 4 requiring the general licensee to implement the aging management activities described in the renewal application and incorporated into the UFSAR. These conditions ensure that the TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System will continue to perform its intended safety functions and provide reasonable assurance of adequate protection of public health and safety throughout the renewal period.

Incremental impacts from continued use of the Standardized Advanced NUHOMS® Horizontal Modular Storage System under a general license for an additional 40 years are not considered significant. When the general licensee follows all procedures and administrative controls, including the conditions established because of this renewal, no effluents are expected from the sealed dry cask systems. Activities associated with cask loading and decontamination may result in some small incremental liquid and gaseous effluents, but these activities will be conducted under 10 CFR parts 50 and 52 reactor operating licenses, and effluents will be controlled within existing reactor site technical specifications. Because reactor sites are relatively large, any incremental offsite doses due to direct radiation exposure from the spent fuel storage casks are expected to be small, and when combined with the contribution from reactor operations, well within the annual dose equivalent of 0.25 mSv (25 mrem) limit to the whole body specified in § 72.104. Incremental impacts on collective occupational exposures due to dry cask spent fuel storage are expected to be only a small fraction of the exposures from operation of the nuclear power station.

The Standardized Advanced NUHOMS® Horizontal Modular Storage System is designed to mitigate the effects of design basis accidents that could occur during storage. Design basis accidents account for human-induced events and the most severe natural phenomena reported for the site and surrounding area. Postulated accidents analyzed for an independent spent fuel storage installation include tornado winds and tornado-generated missiles, a design basis earthquake, a design basis flood, an accidental cask drop, lightning effects, fire, explosions, and other incidents.

During the promulgation of the amendments that added subpart K to 10 CFR part 72 (55 FR 29181; July 18, 1990), the NRC staff assessed the public health consequences of dry cask storage accidents and sabotage events. In the supporting analyses for these amendments, the NRC staff determined that a release from a dry cask storage system would be comparable in magnitude to a release from the same quantity of fuel in a spent fuel storage pool. As a result of these evaluations, the NRC staff determined that, because

of the physical characteristics of the storage casks and conditions of storage that include specific security provisions, the potential risk to public health and safety due to accidents or sabotage is very small.

Considering the specific design requirements for each accident or sabotage condition, the design of the cask would maintain confinement, shielding, and criticality control. If confinement, shielding, or criticality control are maintained, the environmental impacts from an accident would be insignificant.

There are no changes to cask design or fabrication requirements in the renewed initial certificate or Amendment Nos. 1, 3, and 4. Because there are no significant design or process changes, any resulting occupational exposure or offsite dose rates from the implementation of the renewal of the initial certificate and Amendment Nos. 1, 3, and 4 would remain well within the 10 CFR part 20 limits.

In summary, the changes will not result in any radiological or non-radiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990, final rule. Compliance with the requirements of 10 CFR parts 20 and 72 would provide reasonable assurance that adequate protection of public health and safety will continue. The NRC, in its SER for the renewal of the Standardized Advanced NUHOMS® Horizontal Modular Storage System, has determined if the conditions specified in the certificate of compliance to implement these regulations are met, adequate protection of public health and safety will continue to be reasonably assured.

Based on the previously stated assessments and its SER for the requested renewal of the Standardized Advanced NUHOMS® Horizontal Modular Storage System certificates, the NRC has determined that the expiration date of this system in 10 CFR 72.214 can be safely extended for an additional 40 years, and that commercial nuclear power reactor licensees can continue using the system during this period under a general license without significant impacts on the human environment.

D. Alternative to the Action

The alternative to this action is to deny approval of the renewals and not issue the direct final rule. Under this alternative, the NRC would either (1) require general licensees using the Standardized Advanced NUHOMS® Horizontal Modular Storage System to unload the spent fuel from these systems and either return it to a spent fuel pool or re-load it into a different dry storage cask system listed in 10 CFR 72.214; or (2) require that users of the existing Standardized Advanced NUHOMS® Horizontal Modular Storage System request site-specific licensing proceedings to continue storage in these systems.

The environmental impacts of requiring the licensee to unload the spent fuel and either return it to the spent fuel pool or re-load it into another NRC-approved cask system would result in increased radiological doses to workers. These increased doses would be due primarily to direct radiation from the casks while the workers unloaded, transferred, and re-loaded the spent fuel. These activities would consist of transferring the dry storage canisters to a cask-handling building, opening the canister lid welds, returning the canister to a spent fuel pool or dry transfer facility, removing the fuel assemblies, and re-loading them, either into a spent fuel pool storage rack or another NRC-approved dry storage system. In addition to the increased occupational doses to workers, these activities may also result in additional liquid or gaseous effluents.

Alternatively, users of the dry cask storage system would need to apply for a site-specific license. Under this option for implementing the no-action alternative, interested licensees would have to prepare, and the NRC would have to review, each separate license application, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

In summary, the no-action alternative would entail either (1) more environmental impacts than the preferred action from transferring the spent fuel now in the Standardized Advanced NUHOMS® Horizontal Modular Storage System; or (2) cost and administrative impacts from multiple licensing actions that, in aggregate, are likely to be the same as, or more likely greater than, the preferred action.

E. Alternative Use of Resources

Renewal of the initial certificate and Amendment Nos. 1, 3, and 4 to Certificate of Compliance No. 1029 would result in no irreversible commitment of resources.

F. Agencies and Persons Contacted

No agencies or persons outside the NRC were contacted in connection with the preparation of this environmental assessment.

G. Finding of No Significant Impact

The environmental impacts of the action have been reviewed under the requirements in the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' Based on the foregoing environmental assessment, the NRC concludes that this direct final rule, ''List of Approved Spent Fuel Storage Casks: TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System, Certificate of Compliance No. 1029, Renewal of Initial Certificate and Amendment Nos. 1, 3, and 4,'' will not have a significant effect on the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this direct final rule.

IX. Paperwork Reduction Act Statement

This direct final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval number 3150–0132.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

X. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and TN Americas, LLC. These entities do not fall within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

XI. Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask

designs to store spent nuclear fuel if (1) it notifies the NRC in advance; (2) the spent fuel is stored under the conditions specified in the cask's certificate of compliance; and (3) the conditions of the general license are met. A list of NRC-approved cask designs is contained in § 72.214. On January 6, 2003 (68 FR 463), the NRC issued an amendment to 10 CFR part 72 that approved the Standardized Advanced NUHOMS® Horizontal Modular Storage System design by adding it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1029.

On May 22, 2019, TN Americas, LLC requested a renewal of the initial certificate and Amendment Nos. 1, 3, and 4 of the Standardized Advanced NUHOMS® Horizontal Modular Storage System for an additional 40 years beyond the initial certificate term. TN Americas, LLC supplemented its request on December 4, 2019, and July 10, 2020. Because TN Americas, LLC filed its renewal application at least 30 days before the certificate expiration date of February 5, 2023, pursuant to the timely renewal provisions in § 72.240(b), the initial issuance of the certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029 did not expire.

The alternative to this action is to deny approval of the renewal of the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029 and end this direct final rule. Under this alternative, the NRC would either (1) require general licensees using the Standardized Advanced NUHOMS® Horizontal Modular Storage System to unload spent fuel from these systems and return it to a spent fuel pool or re-load it into a different dry storage cask system listed in 10 CFR 72.214; or (2) require that users of the existing Standardized Advanced NUHOMS® Horizontal Modular Storage System request site-specific licensing proceedings to continue storage in these systems. Therefore, the no-action alternative would result in a significant burden on licensees and an additional inspection or licensing caseload on the NRC. In addition, the no action alternative would entail either (1) more environmental impacts than the preferred action from transferring the spent fuel now in the Standardized Advanced NUHOMS® Horizontal Modular Storage System; or (2) cost and administrative impacts from multiple licensing actions that, in aggregate, are likely to be the same as, or more likely greater than, the preferred action.

Approval of this direct final rule is consistent with previous NRC actions. Further, as documented in the preliminary SER and environmental assessment, this direct final rule will have no adverse effect on public health and safety or the environment. This direct final rule has no significant identifiable impact or benefit on other government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of this direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory; therefore, this action is recommended.

XII. Backfitting and Issue Finality

The NRC has determined that the backfit rule (§ 72.62) does not apply to this direct final rule. Therefore, a backfit analysis is not required. This direct final rule renews Certificate of Compliance No. 1029 for the Standardized Advanced NUHOMS® Horizontal Modular Storage System, as currently listed in § 72.214, to extend the expiration date of the initial certificate and Amendment Nos. 1, 3, and 4 by 40 years. The renewed initial certificate and Amendment Nos. 1, 3, and 4 consist of the changes previously described, as set forth in the revised certificate of compliance and technical specifications.

Extending the effective date of the initial certificate and Amendment Nos. 1, 3, and 4 for 40 more years and requiring the implementation of aging management activities does not impose any modification or addition to the design of a cask system's SSC, or to the procedures or organization required to operate the system during the initial 20-year storage period of the system, as authorized by the current certificate. General licensees that have loaded these casks, or that load these casks in the future under the specifications of the applicable certificate, may continue to store spent fuel in these systems for the initial 20-year storage period authorized by the original certificate. The aging management activities required to be implemented by this renewal are only required after the storage cask system's initial 20-year service period ends. As explained in the 2011 final rule that amended 10 CFR part 72 (76 FR 8872, Question I), the general licensee's authority to use a particular storage cask design under an approved certificate of compliance terminates 20 years after the date that the general licensee first loads the particular cask with spent fuel, unless the cask's certificate of compliance is renewed. Because this rulemaking renews the initial certificate and Amendment Nos. 1, 3, and 4, and renewal is a separate licensing action voluntarily implemented by vendors, the renewal of the initial certificate and Amendment Nos. 1, 3, and 4 is not an imposition of new or changed requirements from which these licensees would otherwise be protected by the backfitting provisions in 10 CFR 72.62.

Even if renewal of the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029 could be considered a backfit, TN Americas, LLC, as the holder of the certificate of compliance and vendor of the casks, is not protected by the backfitting provisions in 10 CFR 72.62.

Unlike a vendor, general licensees using the existing systems subject to these renewals would be protected by the backfitting provisions in 10 CFR 72.62 if the renewals constituted new or changed requirements applicable during the initial 20-year storage period. But, as previously explained, renewal of the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029 does not impose such requirements. The general licensee using the initial certificate or Amendment Nos. 1, 3, or 4 of Certificate of Compliance No. 1029 may continue storing material in their respective cask systems for the initial 20-year storage period identified in the applicable certificate or amendment with no changes. If general licensees choose to continue to store spent fuel in Standardized Advanced NUHOMS® Horizontal Modular Storage Systems after the initial 20-year period, these general licensees will be required to implement aging management activities for any cask systems subject to a renewed certificate of compliance, but such continued use is voluntary.

For these reasons, renewing the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029, and imposing the additional conditions previously discussed, does not constitute backfitting under § 72.62, or otherwise represent an inconsistency with the issue finality provisions applicable to combined licenses in 10 CFR part 52. Accordingly, the NRC has not prepared a backfit analysis for this rulemaking.

XIII. Congressional Review Act

This direct final rule is not a rule as defined in the Congressional Review Act.

XIV. Availability of Documents

The documents identified in the following table are available to interested persons, as indicated.

Document	ADAMS accession No.
TN Americas, LLC Renewal Application for the Standardized NUHOMS® Horizontal Modular Storage System Certificate of Compliance No. 1029, dated May 22, 2019.	ML19148A484 (package).
TN Americas, LLC Response to Request for Supplemental Information for the Technical Review of the Application for Certificate of Compliance No. 1029, dated December 4, 2019.	ML19338E132.
TN Americas, LLC Response to Request for Additional Information of the Application for Renewal of the Certificate of Compliance No. 1029, dated May 28, 2020.	ML20192A127.
User Need Memorandum for Rulemaking for Certificate of Compliance Renewal, Initial Issue (Amendment Number 0), Amendment Numbers 1, 3, and 4 to Standardized Advanced NUHOMS® Horizontal Modular Storage System.	ML21067A166.
Preliminary Safety Evaluation Report for the Standardized Advanced NUHOMS® Horizontal Modular Storage System Certificate of Compliance Renewal.	ML21067A167.
Proposed Certificate of Compliance No. 1029, Renewed Initial Certificate	ML21067A168.
Proposed Technical Specifications, Attachment A, Certificate of Compliance No. 1029, Renewed Initial Certificate	ML21067A169.
Proposed Certificate of Compliance No. 1029, Renewed Amendment No. 1	ML21067A170.
Proposed Technical Specifications, Attachment A, Certificate of Compliance No. 1029, Renewed Amendment No. 1	ML21067A171.
Proposed Certificate of Compliance No. 1029, Renewed Amendment No. 3	ML21067A172.
Proposed Technical Specifications, Attachment A, Certificate of Compliance No. 1029, Renewed Amendment No. 3	ML21067A173.
Proposed Certificate of Compliance No. 1029, Renewed Amendment No. 4	ML21067A174.
Proposed Technical Specifications, Attachment A, Certificate of Compliance No. 1029, Renewed Amendment No. 4	ML21067A175.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2021–0108.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance No. 1029 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1029.

Initial Certificate Effective Date: February 5, 2003, superseded by Renewed Initial.

Certificate Effective Date: October 27, 2021.

Amendment Number 1 Effective Date: May 16, 2005, superseded by Renewed.

Amendment Number 1 Effective Date: October 27, 2021.

Amendment Number 2 Effective Date: Amendment not issued by the NRC.

Amendment Number 3 Effective Date: February 23, 2015, superseded by Renewed.

Amendment Number 3 Effective Date: October 27, 2021.

Amendment Number 4 Effective Date: March 12, 2019, superseded by Renewed.

Amendment Number 4 Effective Date: October 27, 2021.

SAR Submitted by: Transnuclear, Inc., now TN Americas, LLC.

Renewal SAR Submitted by: TN Americas, LLC.

SAR Title: Final Safety Analysis Report for the Standardized Advanced NUHOMS® Horizontal Modular Storage System for Irradiated Nuclear Fuel.

Docket Number: 72–1029.

Certificate Expiration Date: February 5, 2023.

Renewed Certificate Expiration Date: February 5, 2063.

Model Number: Standardized Advanced NUHOMS®–24PT1, –24PT4, and –32PTH2.

* * * * *

Dated: August 6, 2021.

For the Nuclear Regulatory Commission.

Daniel H. Dorman,

Acting Executive Director for Operations.

[FR Doc. 2021–17193 Filed 8–12–21; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0669; Project Identifier MCAI–2021–00314–T; Amendment 39–21690; AD 2021–17–07]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Canada Model BD–500–1A10 and BD–500–1A11 airplanes. This AD was prompted by the potential for the flexible hose assembly of the fuel motive flow (MF), installed between the pylon and wing, to be installed twisted in the shroud, which can restrict the flow of fuel for the MF and cause fuel imbalance and damage to the shroud assembly. This AD requires inspecting for damage of the left and right MF fuel line assemblies (including the flexible-hose and shroud assemblies), and replacing damaged parts, as specified in a Transport Canada Civil Aviation (TCCA) AD, which is incorporated by reference. The FAA is issuing this AD

to address the unsafe condition on these products.

DATES: This AD becomes effective August 30, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 30, 2021.

The FAA must receive comments on this AD by September 27, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For material incorporated by reference (IBR) in this AD, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0669.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0669; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jiwan Karunatilake, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

TCCA, which is the aviation authority for Canada, has issued TCCA AD CF–2021–09, dated March 11, 2021 (TCCA AD CF–2021–09) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes.

This AD was prompted by the determination that a new configuration of the pylon-to-wing area MF flexible fuel line assembly was introduced without revision or modification to the installation procedure, potentially resulting in a twisted MF flexible fuel line in the shroud. This can restrict the flow of fuel of the MF, which can cause fuel imbalance and possible damage including abrasion to the shroud assembly. The FAA is issuing this AD to address this condition, which could result in the consequent abrasion of the fuel line and a possible fuel leak; as a result, the electrical harness connectors in the wing area could be a potential ignition source and pose a risk of fire. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

TCCA AD CF–2021–09 describes procedures for a general visual inspection for damage (including permanent deformities) of the left and right MF fuel line assemblies (including the flexible-hose assembly and shroud assembly), and replacement of affected MF fuel line assemblies (including cleaning of the ends of the flexible-hose assembly, injecting grease at both ends of the flexible-hose assembly, and torqueing the aft end of the flexible-hose assembly). This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD because the FAA evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Requirements of This AD

This AD requires accomplishing the actions specified in TCCA AD CF–2021–09 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, TCCA AD CF–2021–09 is incorporated by reference in this AD. This AD requires compliance with TCCA AD CF–2021–09 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Service information required by TCCA AD CF–2021–09 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0669 after this AD is published.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because a twisted MF flexible fuel line in the shroud can restrict the flow of fuel of the MF and cause fuel imbalance and possible damage including abrasion to the shroud assembly and fuel line, resulting in a fuel leak; as a result, the electrical harness connectors in the wing area are a potential ignition source and pose a risk of fire. In addition, the compliance time for the required action is shorter than the time necessary for the public to comment and for publication of the final rule. Therefore, the FAA finds good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reasons stated above, the FAA finds that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–

2021–0669; Project Identifier MCAI–2021–00314–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Jiwan Karunatilake, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act (RFA)

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 5 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
7 work-hours × $85 per hour = $595	$0	$595	$2,975

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
0.5 work-hour × $85 per hour = $42.50	$20,260	$20,302.50

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators. The FAA does not control warranty coverage for affected operators. As a result, the FAA has included all known costs in the cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–17–07 Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Amendment 39–21690; Docket No. FAA–2021–0669; Project Identifier MCAI–2021–00314–T.

(a) Effective Date

This airworthiness directive (AD) becomes effective August 30, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (type certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada Civil Aviation (TCCA) AD CF–2021–09, dated March 11, 2021 (TCCA AD CF–2021–09).

(d) Subject

Air Transport Association (ATA) of America Code 28, Aircraft fuel system.

(e) Reason

This AD was prompted by the potential for the flexible hose assembly of the fuel motive flow (MF), installed between the pylon and wing, to be installed twisted in the shroud, which can restrict the flow of fuel for the MF and cause fuel imbalance and possible damage, including abrasion, to the shroud assembly. The FAA is issuing this AD to address this condition, which could result in abrasion of the fuel line and a possible fuel leak; as a result, the electrical harness connectors in the wing area could be a potential ignition source and pose a risk of fire.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, TCCA AD CF–2021–09.

(h) Exception to TCCA AD CF–2021–09

(1) Where TCCA AD CF–2021–09 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where TCCA AD CF–2021–09 specifies replacing MF fuel line assemblies, this AD requires that replacement before further flight after any damage (including any permanent deformity) is detected.

(i) No Return of Parts

Although the service information referenced in TCCA AD CF–2021–09 specifies to return certain parts to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Airbus Canada's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Related Information

For more information about this AD, contact Jiwan Karunatilake, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Transport Canada Civil Aviation (TCCA) AD CF–2021–09, dated March 11, 2021.

(ii) [Reserved]

(3) For TCCA AD CF–2021–09, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0669.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on August 10, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–17483 Filed 8–11–21; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2019–0111; Airspace Docket No. 19–ASO–23]

RIN 2120–AA66

Establishment of Restricted Area R–5306F; Cherry Point, NC

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This action establishes restricted area R–5306F at Marine Corps Air Station (MCAS) Cherry Point, NC. R–5306F extends from flight level (FL) 180 to FL 290. Restricted area R–5306F overlie the existing restricted area R–5306A, and the adjacent Core Military Operations Area (MOA). Due to altitude constraints, the existing restricted airspace structure around MCAS Cherry Point cannot fully support the training requirements for current legacy aircraft as well as 4th and 5th generation aircraft such as the F–35. In conjunction with R–5306A, restricted area R–5306F will allow for realistic training to enable pilots and aircrews to counter evolving threat nation warfare anti-aircraft capabilities.

DATES: Effective date 0910 UTC, December 2, 2021.

FOR FURTHER INFORMATION CONTACT: Sean Hook, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to

assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes restricted area airspace at Cherry Point, NC, to enhance aviation safety and accommodate essential U.S. Marine Corps training activities.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2019–0111 in the **Federal Register** (85 FR 16918; March 25, 2020), proposing to expand the restricted airspace at MCAS Cherry Point, NC, by establishing restricted area R–5306F, because the altitude constraints of the current airspace structure cannot fully support U.S. Marine Corps training and readiness requirements. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

The Rule

This action amends 14 CFR part 73 by establishing restricted area R–5306F, Cherry Point, NC, to overlie the existing restricted area R–5306A, and the adjacent Core MOA. Restricted area R–5306F extends from FL 180 to FL 290. The time of designation is Monday through Friday, 0800 to 0000 hours, local time; other times by NOTAM.

In conjunction with R–5306A, R–5306F will provide the low-altitude to high-altitude restricted airspace needed to train in the variety of tactics as discussed above.

There are no current Air Traffic Service routes (*i.e.,* jet routes or Q-routes) or preferential IFR routes that are impacted by the restricted area. R–5306F is joint-use special use airspace; meaning that the using agency will return the restricted area to the controlling agency (FAA, Washington ARTCC) on a real-time basis when not in use by the using agency. Supersonic flight will not be conducted in R–5306F.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action of establishing restricted area R–5306F at MCAS Cherry Point, NC, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5f, which categorically excludes from further environmental impact review actions that increase the altitude of special use airspace. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study. The FAA's categorical exclusion declaration and decision for this action is separately documented in a categorical exclusion dated August 25, 2020.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.53 North Carolina [Amended]

■ 2. Section 73.53 is amended as follows:

* * * * *

R–5306F Cherry Point, NC [New]

Boundaries. Beginning at lat. 35°23′16″ N, long. 76°34′39″ W;
to lat. 35°18′16″ N, long. 76°16′39″ W;
to lat. 35°04′31″ N, long. 76°04′29″ W;
to lat. 35°00′31″ N, long. 76°00′59″ W;
to lat. 35°00′22″ N, long. 76°00′51″ W;
thence southwest 3 NM from and parallel to the shoreline
to lat. 34°40′16″ N, long. 76°24′45″ W;
to lat. 34°40′41″ N, long. 76°25′08″ W;
to lat. 34°46′01″ N, long. 76°29′59″ W;
to lat. 35°08′01″ N, long. 76°51′19″ W;
to the point of beginning.

Designated altitudes. FL 180 to FL 290.

Time of designation. Monday through Friday, 0800–0000; other times by NOTAM.

Controlling agency. FAA, Washington ARTCC.

Using agency. USMC, Commanding Officer, U.S. Marine Corps Air Station Cherry Point, NC.

* * * * *

Issued in Washington, DC, on August 9, 2021.

George Gonzalez,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2021–17251 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 241

[Release No. 34–92565]

Procedures for the Commission's Use of Certain Authorities Under Rule 21F–3(b)(3) and Rule 21F–6 of the Securities Exchange Act of 1934

AGENCY: Securities and Exchange Commission.

ACTION: Policy statement.

SUMMARY: The Securities and Exchange Commission (''Commission'' or ''SEC'') is issuing this statement to clarify how the SEC will proceed when addressing certain issues under Exchange Act Rule 21F–3(b)(3) and Exchange Act Rule 21F–6 while the staff is preparing and the Commission is considering potential amendments to those rules (''Interim Policy-Review Period''). These procedures will remain in effect until withdrawn by the Commission.

DATES: The policy statement is effective: August 13, 2021.

FOR FURTHER INFORMATION CONTACT: Emily Pasquinelli, Acting Chief in the Office of the Whistleblower, Division of Enforcement, at (202) 551–5973; William K. Shirey, Counsel to the Solicitor, Office of the General Counsel, at (202) 551–5043; Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to the Dodd-Frank Consumer Protection and Wall Street

Reform Act of 2010 (''Dodd-Frank Act''), Section 21F was added to the Securities Exchange Act of 1934 (''Exchange Act''), 15 U.S.C. 78u–1 *et seq.,* to establish a new SEC whistleblower award program. Section 21F provides that, pursuant to regulations adopted by the SEC, a monetary award shall be paid to any eligible whistleblower who provides the SEC with original information about a securities law violation that leads to the SEC's success in obtaining a monetary order of more than a million dollars in an SEC judicial or administrative enforcement action (''covered action''). If an eligible whistleblower qualifies for an award, the SEC must pay an award that is at least 10%, but no more than 30%, of the amount of the monetary sanctions collected in the SEC enforcement action.

Section 21F further provides that if the SEC makes a whistleblower award in connection with its own enforcement action, the whistleblower becomes potentially eligible for an award in connection with any related enforcement actions (''related actions'') that are successfully litigated using the whistleblower's same original information. The potential related enforcement actions must be brought either by a self-regulatory organization or certain statutorily identified governmental authorities (such as the U.S. Department of Justice or a state attorney general in connection with a criminal proceeding).[1]

In May 2011, the Commission adopted rules to govern the operation of the whistleblower award program. In September 2020, the Commission adopted various amendments to the Whistleblower Program rules, including two amendments that whistleblower advocates and others have asserted are unfair to whistleblowers and may risk reducing the willingness of individuals to blow the whistle. These amendments were made to: (1) Exchange Act Rule 21F–3, which addresses the criteria for making an award based on a whistleblower's contributions to the successful resolution of a related action; and (2) Exchange Act Rule 21F–6, which establishes the criteria that the Commission may consider when determining the appropriate award amount.

• *Relevant Amendment to Exchange Act Rule 21F–3.* The 2020 Amendments added new subparagraph (c) to Rule 21F–3 to govern situations where a whistleblower has filed a claim for an award in connection with a potential related action but that action is potentially also covered by a second, separate award program (such as, for example, the federal whistleblower award program that the Internal Revenue Service administers, *see* 26 U.S.C. 7623). New paragraph (c) authorizes the Commission to determine, based on the facts and circumstances of the claims and misconduct at issue in the potential related action (among other factors), whether the Commission's whistleblower program or the other whistleblower program has the more ''direct or relevant connection to the [related] action.'' And responsibility for making an award in connection with the potential related action will then rest with whichever award program is determined to have the more direct or relevant connection to the action.

• *Relevant Amendment to Exchange Act Rule 21F–6.* The 2020 Amendments added language to permit the Commission to consider, in its discretion, the dollar amount of a potential award when making an award determination. Before this amendment, the text of the rule (with one limited exception) did not expressly afford the Commission authority to consider the potential dollar amount of an award when determining awards; rather, the text of the rule generally referred to setting awards as a percentage of the monetary sanctions recovered.

II. Procedures Available During the Interim Policy-Review Period

On August 2, 2021, Chair Gensler issued a public statement advising that he has directed the staff to prepare for the Commission's consideration later this year potential changes to Rules 21F–3(b)(3) and Rule 21F–6 to address policy concerns raised by whistleblower advocates and others about possible adverse effects of the 2020 Amendments.[2]

While the staff is preparing and the Commission is considering potential additional rulemaking, the procedures discussed below are available to whistleblowers with claims pending during the Interim Policy-Review Period so that they are not disadvantaged under the components of Rule 21F–3(b)(3) and Rule 21F–6 that may be revised. These interim procedures are consistent with the SEC's overarching goal of protecting investors and the United States capital markets by encouraging whistleblowers to come forward to report violations of the federal securities laws and then rewarding them when their information leads to successful enforcement actions.

A. Exchange Act Rule 21F–3(b)(3)

For any claim that may be subject to Rule 21F–3(b)(3) during the Interim Policy-Review Period, the Commission directs as follows:

1. Before providing a preliminary determination to a claimant, or a proposed recommendation to the Commission, the staff shall consider whether to recommend that the Commission's exemptive authority under Section 36(a) of the Exchange Act[3] should be utilized to permit an award on a potential related action irrespective of the limitations of Rule 21F–3(b)(3) if:

(a) The alternative whistleblower program has an award cap or award range that could disadvantage the particular claimant; [4] or

(b) the Commission is aware or the claimant demonstrates a likelihood that a condition or exclusion would apply to his or her award claim under the alternative award program and the staff determines that the claimant would likely obtain an award were he or she permitted to proceed under the SEC's award program.

2. For any other award claim under Rule 21F–3(b)(3) for which the staff determines that an alternative whistleblower program has a ''more direct or relevant connection'' to the potential related action than the Commission's award program does, the staff will inform the claimant of its assessment. The claimant may then request that the related-action award claim held in abeyance during the Interim Policy-Review Period.[5] Further, any related-action award claim that is held in abeyance shall not impact the

[1] *See* Exchange Act 21F(a)(5) (defining related action); Exchange Act Rule 21F–3(b)(1) (same).

[2] *See also* SEC's Spring 2021 Regulatory Agenda (publicly available at: *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=3235-AN03*) (''The Commission is considering additional amendments to the rules governing the Whistleblower Program established by the Dodd-Frank Act.'').

[3] In pertinent part, Section 36(a) provides that ''by rule, regulation, or order, may conditionally or unconditionally exempt any person . . . from any provision or provisions of [the Exchange Act] or of any rule or regulation thereunder, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.''

[4] *See, e.g.,* 12 U.S.C. 4205(d)(1) (establishing a whistleblower award program in connection with the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, but capping awards at $1.6 million).

[5] The Commission contemplates that there should be no impact on the timely processing of any related-action award claim that the staff deems to have a ''more direct or relevant connection to the Commission's whistleblower program.'' However, if a majority of the Commission should subsequently disagree with that determination, the claimant shall be notified and may request to have the related-action award claim held in abeyance during the Interim Policy-Review Period.

timely processing of any award claim arising from a covered Commission enforcement action that is successfully litigated using the claimant's same original information.

B. Exchange Act Rule 21F–6

With respect to Rule 21F–6, the Commission at the time it adopted the 2020 rulemaking amendments explained that the amendment in question was a clarification of discretionary authority the Commission already possessed.[6] The Commission anticipates that, going forward, it will continue its practice of considering dollar amounts only in connection with provisions of the rules that explicitly contemplate the use of such discretion to raise awards (*i.e.,* law enforcement interest prong of 21F–6(a)(3) and the application of the presumption embodied in Rule 21F–6(c)). In the unlikely event that the staff or the Commission should consider deviating from this practice, the staff will inform the claimant that such action is being considered. The claimant may then request that the matter be held in abeyance during the Interim Policy-Review Period.

III. Other Matters

Publication for notice and comment is not required under the Administrative Procedure Act (''APA'') pursuant to the exemption for agency rules of organization, procedure, or practice.[7] It follows that the requirements of the Regulatory Flexibility Act do not apply.[8] The effective date is August 13, 2021. In accordance with the APA,[9] we find that there is good cause to establish an effective date less than 30 days after publication. The Commission believes that establishing an effective date less than 30 days after publication of this document is necessary to clarify how the SEC will proceed when addressing certain issues under Exchange Act Rule 21F–3(b)(3) and Exchange Act Rule 21F–6 while the staff is preparing and the Commission is considering potential amendments to those rules.

The Commission has determined that the foregoing relates only to agency procedures and does not substantially affect the rights or obligations of non-agency parties. The foregoing is therefore not a ''rule'' under the Congressional Review Act, 5 U.S.C. 804(3)(C).

Finally, the Commission has adopted the foregoing under the authority set forth in Sections 3(b), 21F, and 23(a) of the Exchange Act.

By the Commission.

Dated: August 5, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–17019 Filed 8–12–21; 8:45 am]

BILLING CODE 8011–01–P

[6] The extent to which the amendment was a clarification was a point of disagreement at the time that the Commission adopted the amended rules in 2020.

[7] 5 U.S.C. 553(b)(A).

[8] 5 U.S.C. 601–612.

[9] 5 U.S.C. 553(d)(3).

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2021–0598]

RIN 1625–AA08

Special Local Regulation; Cumberland River, Ashland City, TN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for navigable waters on the Cumberland River. The special local regulation is needed to protect personnel, vessels, and the marine environment from potential hazards created by the Riverbluff Triathlon marine event. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Ohio Valley.

DATES: This rule is effective on August 29, 2021 from 6 a.m. to 10 a.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0598 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Third Class Benjamin Gardner, Marine Safety Detachment Nashville, U.S. Coast Guard; telephone 615–736–5421, email *Benjamin.t.gardner@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
MM Mile Marker
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this regulation by August 29, 2021 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to ensure the safety of the participants and vessels during the Riverbluff Triathlon. It is impracticable to publish an NPRM because we must establish this special local regulation by August 29, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with Riverbluff Triathlon on August 29, 2021, will be a safety concern from MM 157.0 to MM 159.0 of the Cumberland River for 4 hours. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the special local regulation while the event is taking place.

IV. Discussion of the Rule

This rule establishes a special local regulation from MM 157.0 to MM 159.0 on the Cumberland River. The safety zone will be in effect on August 29, 2021 from 6 a.m. to 10 a.m.. The duration of the zone is intended to protect participants, and the marine environment in these navigable waters while the Riverbluff Triathlon is taking place. No vessel or person will be permitted to enter the regulated area without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and the time-of-day of the special local regulation. Vessel traffic will be able to safely transit around the this special local regulation which would impact a small designated area of the Cumberland River before or after the time of the event. Moreover the Coast Guard will issue a Broadcast the Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation lasting only 4 hours that will prohibit entry within a 2 mile segment of the Cumberland River. It is categorically excluded from further review under paragraph [L61] and [L63a] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T08–0598 to read as follows:

§ 100.T08–0275 Cumberland River MM 157 to MM 159, Ashland City, TN.

(a) *Regulated area.* The regulations in this section apply to the following area: all waters of the Cumberland River from MM 157.0 to 159.0.

(b) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this

section unless authorized by the Captain of the Port Sector Ohio Valley or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by phone at 1–800–253–7465. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) The COTP will provide notice of the regulated area through advanced notice via broadcast notice to mariners.

(d) *Enforcement period.* This section will be enforced on August 29, 2021, from 6 a.m. to 10 a.m.

Dated: August 5, 2021.

A.M. Beach,

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

[FR Doc. 2021–17354 Filed 8–12–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0608]

RIN 1625–AA00

Temporary Safety Zone; Ferdon Wedding Fireworks Display, Harbor Springs, MI; Sector Sault Sainte Marie Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 250-foot radius of a fireworks display off shore near Little Harbor Club in Harbor Springs, MI. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by fireworks diplay. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sault Sainte Marie or a designated representative.

DATES: This rule is effective from 6 p.m. through 11:59 p.m. on August 28, 2021. It will be enforced from 8 p.m. through 10 p.m. on that day.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0608 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Deaven Palenzuela, U.S. Coast Guard Sector Sault Sainte Marie Waterways Management, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event sponsor notified the Coast Guard with insufficient time to accommodate the comment period. Delaying the effective date of this rule would be contrary to the public interest and the rule's objectives of protecting safety of life on the navigable waters, including protection of persons and vessels in vicinity of the fireworks display. It is impracticable to publish an NPRM because we must establish this safety zone by August 28, 2021. Delay of the effective date would inhibit the Coast Guard's ability to protect spectators and vessels from the hazards associated with a fireworks display with an expected fall-out area over the water.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because action is needed to establish a safety zone in order to protect the public from the hazards associated with the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sault Sainte Marie (COTP) has determined that potential hazards associated with a fireworks display on August 28, 2021, will be a safety concern for anything within a 250-foot radius of the navigable waters surrounding the fireworks launch site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone that will be enforced from 8 p.m. through 10 p.m. on August 28, 2021. The safety zone will cover all navigable waters within 250-feet of a fireworks display off shore Little Harbor Club in Harbor Springs, MI in position 45°25′34.00″ N 84°59′23.49″ W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in the safety zone proceeding, during and immediately after the fireworks display.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area off shore Little Harbor Club. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions

with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone lasting only 2 hours that will prohibit entry within a 250-foot radius of a fireworks display off shore near Little Harbor Club in Harbor Springs, MI. It is categorically excluded from further review under paragraph L[60(a)] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0608 to read as follows:

§ 165.T09–0608 Ferdon Wedding Fireworks, Off Shore Little Harbor Club, Harbor Springs, MI.

(a) *Location.* The following area is a temporary safety zone: All navigable water within 250 feet of the fireworks launching location in position 45°25′34.00″ N 84°59′23.49″ W (NAD 83)

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

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within the safety zone described in paragraph (a) is prohibited unless authorized by the Captain of the Port, Sault Sainte Marie or his designated representative.

(2) Before a vessel operator may enter or operate within the safety zone, they must obtain permission from the Captain of the Port, Sault Sainte Marie, or his designated representative via VHF Channel 16 or telephone at (906) 635–3233. Vessel operators given permission to enter or operate in the safety zone must comply with all orders given to them by the Captain of the Port, Sault Sainte Marie or his designated representative.

(d) *Enforcement period.* This section will be enforced from 8 p.m. through 10 p.m. on August 28, 2021.

Dated: August 9, 2021.

A.R. Jones,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2021–17336 Filed 8–12–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0327]

RIN 1625–AA00

Safety Zone; Patapsco River, Baltimore, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of the Patapsco River. This action is necessary to provide for the safety of life on these navigable waters near the Francis Scott Key (I–695) Bridge, Baltimore, MD, while work crews install power transmission lines crossing over the Patapsco River from September 1, 2021 through November 17, 2021. This regulation prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Maryland—National Capital Region a designated representative.

DATES: This rule is effective from September 1, 2021, through November 17, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0327 in the ''SEARCH'' box and click ''SEARCH.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Ron Houck, Sector Maryland—National Capital Region Waterways Management Division, U.S. Coast Guard; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

On May 12, 2021, Baltimore Gas and Electric Company (BGE) provided the Coast Guard with details concerning activities associated with the installation of two new overhead power transmission lines crossing over the Patapsco River from the vicinity of the Hawkins Point terminal Station on the west side of the Patapsco River to a location just north of Sollers Point Terminal Station on the east side of the Patapsco River, to be conducted from September 1, 2021, through November 17, 2021. This installation process requires the temporary closure of the navigation channel near the Francis Scott Key (I–695) Bridge and the temporary closure of other portions of the Patapsco River nearby, including on multiple days during the stated installation period. In response, on May 16, 2021, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Safety Zone; Patapsco River, Baltimore, MD,'' (86 FR 31999). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this installation of overhead power transmission lines. During the comment period that ended July 16, 2021, we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the installation of power transmission lines over the Patapsco River adjacent to Francis Scott Key (I–695) Bridge conducted within the federal navigation channel and other portions of the river nearby. Such hazards include low-hanging or falling ropes and cables, helicopter rotor downwash and noise, dangerous projectiles, and or other debris.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP Maryland—National Capital Region has determined that potential hazards associated with the overhead power transmission line installation work will be a safety concern for anyone transiting the Patapsco River. The purpose of this rule is to ensure safety of vessels and the navigable waters in the safety zone before, during, and after the scheduled work.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published May 16, 2021. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from September 1, 2021, through November 17, 2021, to be enforced while BGE installs overhead power transmission lines over the river. On days the safety zone will be enforced, the affected area of the river will be closed during the dates and times scheduled. These dates and times may change due to weather, or for any reason that the primary dates and times could not be used. Alternative dates have been provided in the event the primary dates can not be used. Exact dates and times would be announced by broadcast notice to mariners, between one and five days in advance of the scheduled date, to alert mariners of the change. The safety zone will cover all navigable waters of the Patapsco River, encompassed by a line connecting the following points beginning at the shoreline at Thoms Cove at position latitude 39°12′36″ N, longitude 076°32′50″ W, thence east and south along the shoreline to Hawkins Point at latitude 39°12′40″ N, longitude 076°31′58″ W, thence northeast across the Patapsco River to Coffin Point at latitude 39°13′55″ N, longitude 076°30′18″ W, thence west and north along the shoreline to Sollers Point at latitude 39°14′01″ N, longitude 076°30′59″ W, thence west across the Patapsco River to and terminating at the point of origin, located at Baltimore, MD.

This rule provides additional information about areas within the safety zone and their definitions. These areas include ''Area 1,'' ''Area 2,'' ''Area 3,'' ''Area 4,'' ''Area 5,'' and ''Area 6.'' A diagram of the tower locations is provided in the docket folder.

The duration of the rule and enforcement of the zone is intended to ensure the safety of vessels and these navigable waters while the activities associated with the installation of two new overhead power transmission lines crossing over the Patapsco River are being conducted. The COTP will notify the public that the safety zone will be enforced by all appropriate means to the affected segments of the public, as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include, but are not limited to, Broadcast Notice to Mariners. Vessels or persons violating this rule are subject to the penalties set forth in 46 U.S.C. 70036 (previously codified in 33 U.S.C. 1232) and 46 U.S.C. 70052 (previously codified in 50 U.S.C. 192).

Except for craft and equipment operated by BGE, or its subcontractors, no vessel or person will be permitted to enter the safety zone without obtaining

permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, duration, day-of-week, and time of year of the safety zone, which will impact a small designated area of the Patapsco River during certain weekdays (Mondays through Fridays, including holidays). Vessels or persons will not be allowed to enter or transit a portion of the Patapsco River for a total 97 enforcement-hours, over an 11-week period from September 1, 2021, through November 17, 2021, during active overhead power transmission line installation activities as described in the text above. The closures are scheduled to impose the least amount of impact on vessel operations in Baltimore Harbor. Due to the nature of the work and the hazards it presents to the workers and the public, the COTP has identified the need to close the Patapsco River in the vicinity of the overhead power line crossing while this work is ongoing. Moreover, the Coast Guard will issue Local Notices to Mariners and a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 97 total enforcement hours that will prohibit entry within portions of the Patapsco River. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0327 to read as follows:

§ 165.T05–0327 Safety Zone; Patapsco River, Baltimore, MD.

(a) *Location.* The following area is a safety zone: All navigable waters of the Patapsco River, encompassed by a line connecting the following points beginning at the shoreline at Thoms Cove at position latitude 39°12′36″ N, longitude 076°32′50″ W, thence east and south along the shoreline to Hawkins Point at latitude 39°12′40″ N, longitude 076°31′58″ W, thence northeast across the Patapsco River to Coffin Point at latitude 39°13′55″ N, longitude 076°30′18″ W, thence west and north along the shoreline to Sollers Point at latitude 39°14′01″ N, longitude 076°30′59″ W, thence west across the Patapsco River to and terminating at the point of origin, located at Baltimore, MD. These coordinates are based on datum NAD 83. The following areas are within the safety zone:

(1) *Area 1.* All navigable waters within the safety zone described in paragraph (a) of this section, located between Tower 1 at latitude 39°12′35.73″ N, longitude 076°32′30.00″ W, and Tower 2 at latitude 39°12′46.87″ N, longitude 076°32′14.05″ W.

(2) *Area 2.* All navigable waters within the safety zone described in paragraph (a) of this section, located between Tower 2 at latitude 39°12′46.87″ N, longitude 076°32′14.05″ W, and Tower 3 at latitude 39°12′58.56″ N, longitude 076°31′58.74″ W.

(3) *Area 3.* All navigable waters within the safety zone described in paragraph (a) of this section, located between Tower 3 at latitude 39°12′58.56″ N, longitude 076°31′58.74″ W, and Tower 4 at latitude 39°13′13.79″ N, longitude 076°31′38.79″ W.

(4) *Area 4.* All navigable waters within the safety zone described in paragraph (a) of this section, located between Tower 4 at latitude 39°13′13.79″ N, longitude 076°31′38.79″ W, and Tower 5 at latitude 39°13′26.61″ N, longitude 076°31′21.98″ W.

(5) *Area 5.* All navigable waters within the safety zone described in paragraph (a) of this section, located between Tower 5 at latitude 39°13′26.61″ N, longitude 076°31′21.98″ W, and Tower 6 at latitude 39°13′39.43″ N, longitude 076°31′05.18″ W.

(6) *Area 6.* All navigable waters within the safety zone described in paragraph (a) of this section, located between Tower 6 at latitude 39°13′39.43″ N, longitude 076°31′05.18″ W, and Tower 7 at latitude 39°13′52.14″ N, longitude 076°30′48.69″ W.

(b) *Definitions.* As used in this section—

Captain of the Port (COTP) means the Commander, U.S. Coast Guard Sector Maryland—National Capital Region.

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Maryland—National Capital Region (COTP) in the enforcement of the safety zone.

Tower means a Baltimore Gas and Electric Company steel monopole structure used to support overhead high voltage transmission lines, located between the vicinity of the Hawkins Point Terminal Station on the west side of the Patapsco River and a location just north of Sollers Point Terminal Station on the east side of the Patapsco River.

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

(2) To seek permission to enter, contact the COTP or the COTP's representative by telephone at 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement officials.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement periods.* (1) Paragraphs (a)(1) through (6) of this section will be enforced:

(i) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 1, 2021. If necessary due to inclement weather or other reason on September 1, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 7, 2021;

(ii) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 2, 2021. If necessary due to inclement weather or other reason on September 2, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 8, 2021;

(iii) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 13, 2021. If necessary due to inclement weather or other reason on September 13, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 15, 2021;

(iv) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 20, 2021. If necessary due to inclement weather or other reason on September 20, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 22, 2021;

(v) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 24, 2021. If necessary due to inclement weather or other reason on September 24, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on September 28, 2021;

(vi) From 9 a.m. to 10:30 a.m. on September 27, 2021. If necessary due to inclement weather or other reason on September 27, 2021, it will be enforced from 9 a.m. to 10:30 a.m. on September 29, 2021;

(vii) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on October 12, 2021. If necessary due to inclement weather or other reason on October 12, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on October 14, 2021;

(viii) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on October 13, 2021. If necessary due to inclement weather or other reason on October 13, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on October 15, 2021;

(ix) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on October 18, 2021. If necessary due to inclement weather or other reason on October 18, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on October 20, 2021;

(x) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on October 25, 2021. If necessary due to inclement weather or other reason on October 25, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on October 27, 2021;

(xi) From 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on November 1, 2021. If necessary due to inclement weather or other reason on November 1, 2021, it will be enforced from 9 a.m. to 10:30 a.m. and from 1 p.m. to 2:30 p.m. on November 3, 2021; and

(xii) From 9 a.m. to 10:30 a.m. on November 3, 2021. If necessary due to inclement weather or other reason on November 3, 2021, it will be enforced from 9 a.m. to 10:30 a.m. on November 5, 2021.

(2) Paragraph (a)(1) of this section will be enforced:

(i) From 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on October 5, 2021. If necessary due to inclement weather or other reason on October 5, 2021, it will be enforced from 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on October 7, 2021;

(ii) From 6 a.m. to 6:30 a.m., from 7 a.m. to 7:30 a.m., from 8 a.m. to 8:30 a.m., and from 9 a.m. to 9:30 a.m. on October 8, 2021. If necessary due to inclement weather or other reason on October 8, 2021, it will be enforced from 6 a.m. to 6:30 a.m., from 7 a.m. to 7:30 a.m., from 8 a.m. to 8:30 a.m., and from 9 a.m. to 9:30 a.m. on October 12, 2021;

(iii) From 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 10:30 a.m. on November 9, 2021. If necessary due to inclement weather or other reason on November 9, 2021, it will be enforced from 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 10:30 a.m. on November 11, 2021; and

(iv) From 6 a.m. to 6:30 a.m., from 7 a.m. to 7:30 a.m., from 8 a.m. to 8:30 a.m., and from 9 a.m. to 9:30 a.m. on November 12, 2021. If necessary due to inclement weather or other reason on November 12, 2021, it will be enforced from 6 a.m. to 6:30 a.m., from 7 a.m. to 7:30 a.m., from 8 a.m. to 8:30 a.m., and from 9 a.m. to 9:30 a.m. on November 16, 2021.

(3) Paragraph (a)(2) of this section will be enforced:

(i) From 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on October 5, 2021. If necessary due to inclement weather or other reason on October 5, 2021, it will be enforced from 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on October 7, 2021;

(ii) From 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on October 8, 2021. If necessary due to inclement weather or other reason on October 8, 2021, it will be enforced from 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on October 12, 2021;

(iii) From 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on November 9, 2021. If necessary due to inclement weather or other reason on November 9, 2021, it will be enforced from 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on November 11, 2021; and

(iv) From 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on November 12, 2021. If necessary due to inclement weather or other reason on November 12, 2021, it will be enforced from 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on November 16, 2021.

(4) Paragraph (a)(3) of this section will be enforced:

(i) From 6 a.m. to 7 a.m., from 7:30 a.m. to 8:30 a.m., from 9 a.m. to 10 a.m., and from 10:30 a.m. to 11:30 a.m. on October 6, 2021. If necessary due to inclement weather or other reason on October 6, 2021, it will be enforced from 6 a.m. to 7 a.m., from 7:30 a.m. to 8:30 a.m., from 9 a.m. to 10 a.m., and from 10:30 a.m. to 11:30 a.m. on October 8, 2021;

(ii) From 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., from 5 p.m. to 5:30 p.m., from 6 p.m. to 6:30 p.m., and from 7 p.m. to 7:30 p.m. on October 8, 2021. If necessary due to inclement weather or other reason on October 8, 2021, it will be enforced from 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., from 5 p.m. to 5:30 p.m., from 6 p.m. to 6:30 p.m., and from 7 p.m. to 7:30 p.m. on October 12, 2021;

(iii) From 6 a.m. to 7 a.m., from 7:30 a.m. to 8:30 a.m., from 9 a.m. to 10 a.m., and from 10:30 a.m. to 11:30 a.m. on November 10, 2021. If necessary due to inclement weather or other reason on November 10, 2021, it will be enforced from 6 a.m. to 7 a.m., from 7:30 a.m. to 8:30 a.m., from 9 a.m. to 10 a.m., and from 10:30 a.m. to 11:30 a.m. on November 12, 2021; and

(iv) From 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., from 5 p.m. to 5:30 p.m., from 6 p.m. to 6:30 p.m., and from 7 p.m. to 7:30 p.m. on November 12, 2021. If necessary due to inclement weather or other reason on November 12, 2021, it will be enforced from 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., from 5 p.m. to 5:30 p.m., from 6 p.m. to 6:30 p.m., and from 7 p.m. to 7:30 p.m. on November 16, 2021.

(5) Paragraph (a)(4) of this section will be enforced:

(i) From 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on October 6, 2021. If necessary due to inclement weather or other reason on October 5, 2021, it will be enforced from 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on October 8, 2021;

(ii) From 6 a.m. to 6:30 a.m., from 7 a.m. to 7:30 a.m., from 8 a.m. to 8:30 a.m., and from 9 a.m. to 9:30 a.m. on October 11, 2021. If necessary due to inclement weather or other reason on October 11, 2021, it will be enforced from 6 a.m. to 6:30 a.m., from 7 a.m. to 7:30 a.m., from 8 a.m. to 8:30 a.m., and from 9 a.m. to 9:30 a.m. on October 13, 2021;

(iii) From 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on November 10, 2021. If necessary due to inclement weather or other reason on November 10, 2021, it will be enforced from 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on November 12, 2021; and

(iv) From 6 a.m. to 6:30 a.m., from 7 a.m. to 7:30 a.m., from 8 a.m. to 8:30 a.m., and from 9 a.m. to 9:30 a.m. on November 15, 2021. If necessary due to inclement weather or other reason on November 15, 2021, it will be enforced from 6 a.m. to 6:30 a.m., from 7 a.m. to 7:30 a.m., from 8 a.m. to 8:30 a.m., and from 9 a.m. to 9:30 a.m. on November 17, 2021.

(6) Paragraph (a)(5) of this section will be enforced:

(i) From 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on October 7, 2021. If necessary due to inclement weather or other reason on October 7, 2021, it will be enforced from 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on October 11, 2021;

(ii) From 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on October 11, 2021. If necessary due to inclement weather or other reason on October 11, 2021, it will be enforced from 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on October 13, 2021;

(iii) From 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on November 11, 2021. If necessary due to inclement weather or other reason on November 11, 2021, it will be enforced from 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on November 15, 2021; and

(iv) From 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on November 15, 2021. If necessary due to inclement weather or other reason on November 15, 2021, it will be enforced from 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on November 17, 2021.

(7) Paragraph (a)(6) of this section will be enforced:

(i) From 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on October 7, 2021. If

necessary due to inclement weather or other reason on October 7, 2021, it will be enforced from 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on October 11, 2021;

(ii) From 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., from 5 p.m. to 5:30 p.m., from 6 p.m. to 6:30 p.m., and from 7 p.m. to 7:30 p.m. on October 11, 2021. If necessary due to inclement weather or other reason on October 11, 2021, it will be enforced from 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., from 5 p.m. to 5:30 p.m., from 6 p.m. to 6:30 p.m., and from 7 p.m. to 7:30 p.m. on October 13, 2021;

(iii) From 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on November 11, 2021. If necessary due to inclement weather or other reason on November 11, 2021, it will be enforced from 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on November 15, 2021; and

(iv) From 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., and from 5 p.m. to 5:30 p.m. on November 15, 2021. If necessary due to inclement weather or other reason on November 15, 2021, it will be enforced from 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., and from 5 p.m. to 5:30 p.m. on November 17, 2021.

Dated: August 3, 2021.

David E. O'Connell,

Captain, U.S. Coast Guard, Captain of the Port Maryland—National Capital Region.

[FR Doc. 2021–17229 Filed 8–12–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2020–0574; FRL–8730–02–R3]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Emissions Statement Certification for the 2015 Ozone National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision formally submitted by the District of Columbia Department of Energy and the Environment (DOEE). The revision provides the District's certification that its existing emissions statement program satisfies the emissions statement requirements of the Clean Air Act (CAA) for the 2015 ozone National Ambient Air Quality Standard (NAAQS). EPA is approving the District's emissions statement program certification for the 2015 ozone NAAQS as a SIP revision in accordance with the requirements of the CAA.

DATES: This final rule is effective on September 13, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2020–0574. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Serena Nichols, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2053. Ms. Nichols can also be reached via electronic mail at *Nichols.Serena@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On March 11, 2021 (86 FR 13843), EPA published a notice of proposed rulemaking (NPRM) for the District of Columbia. In the NPRM, EPA proposed approval of the District's certification that the District's emissions statement regulation meets the emissions statement requirement of section 182(a)(3)(B) of the CAA for the 2015 ozone NAAQS. The formal SIP revision was submitted by the District of Columbia, through the Department of Energy and the Environment (DOEE), on June 4, 2020.

II. Summary of SIP Revision and EPA Analysis

On June 4, 2020, the District, through DOEE, submitted as a formal SIP revision, a statement certifying that the District's existing SIP-approved emissions statement program covers the District's portion of the Washington, DC-MD-VA nonattainment area for the 2015 ozone NAAQS and is at least as stringent as the requirements of CAA section 182(a)(3)(B). In its submittal, the District states that 20 District of Columbia Municipal Regulations (DCMR) section 500.9 contains emissions reporting requirements consistent with CAA section 182(a)(3)(B)(i), and that 20 DCMR section 500.9 is approved into the District's SIP. See 40 CFR 52.2420(c). EPA first approved the District's emissions statements requirements, now found at 20 DCMR section 500.9, into the District's SIP on May 26, 1995 (60 FR 27944).[1] See also 40 CFR 52.470.

EPA's review of the District's submittal finds that the District's existing, SIP-approved emissions statement program at 20 DCMR section 500.9 satisfies the emission statement requirements of CAA section 182(a)(3)(B) for the 2015 ozone NAAQS. The District's regulation requires the owner of any stationary source located in the District that emits 25 tons per year (tpy) or more of volatile organic compounds (VOC) or nitrogen oxides (NO_X) to submit an emissions statement to the Mayor by April 15 of each year for the emissions discharged during the previous calendar year. Emissions statements are required to be prepared and submitted in accordance with 20 DCMR section 500.9.

These emissions statements are required to be submitted annually for the previous calendar year and, at a minimum, must contain the following: (1) Certification that the information in the statement is accurate to the best knowledge of the individual certifying the statement as well as the certifying individual's name and contact information; (2) source identification information including name, physical location, mailing address of the facility, latitude and longitude, and standard industrial classification code(s); (3) operating information including percentage annual throughput by season, days per week on the normal operating schedule, hours per day during the normal operating schedule, and hours per year during the normal operating schedule; (4) process rate data including annual process rate and peak ozone season daily process rate; (5) control equipment information; and (6) emissions information including, but not limited to, estimated actual emissions of NO_X and VOC in tpy and

[1] 20 DCMR sections 500.4 through 500.6 were also approved into the District's SIP on January 26, 1995 (60 FR 5134) and October 27, 1999 (64 FR 57777), respectively. These provisions concern reporting requirements related to the transfer of gasoline products.

pounds per typical ozone season day. These reporting requirements in 20 DCMR section 500.9 meet the requirements of CAA section 182(a)(3)(B)(i).

As allowed by CAA section 182(a)(3)(B)(ii), the District has waived the emissions reporting requirement for stationary sources emitting less than 25 tpy of NO_X or VOCs because the District includes these emissions in reports to EPA. CAA section 182(a)(3)(B)(ii) allows the State to waive the application of clause (i) to any class or category of stationary sources which emit less than 25 tons per year of VOC or NO_X if the State, in its submissions under subparagraphs (1) or (3)(A), provides an inventory of emissions from such class or category of sources, based on the use of the emission factors established by the Administrator or other methods acceptable to the Administrator.

As noted in the District's June 4, 2020 submittal, pursuant to the Air Emissions Reporting Requirements rule at 40 CFR part 51, the District is required to submit emissions inventories for criteria pollutants to EPA's Emissions Inventory System (EIS), and that sources emitting less than 25 tpy of NO_X or VOC are included in these inventories as area sources. The submission also notes that emissions from these sources are calculated using emission factors approved by the Administrator. These small stationary sources are therefore addressed in accordance with CAA section 182(a)(3)(B)(ii).

Therefore, EPA has determined that the District's existing emissions statement program, as set forth at 20 DCMR section 500.9, which is currently in the District's SIP, and the District's reporting for sources emitting less than 25 tpy of NO_X or VOC, meet the emissions statement requirements in CAA section 182(a)(3)(B) for the 2015 ozone NAAQS. EPA is approving, as a SIP revision, the District's June 4, 2020 emissions statement program certification as meeting the requirements of CAA section 182(a)(3)(B) for the 2015 ozone NAAQS.

Other specific requirements of DOEE's June 4, 2020 submittal and the rationale for EPA's proposed action are explained in the NPRM and will not be restated here. No public comments were received on the NPRM.

III. Final Action

EPA is approving, as a SIP revision, the District of Columbia's June 4, 2020 emissions statement certification for the 2015 ozone NAAQS as approvable under CAA section 182(a)(3)(B). The District's emissions statement certification certifies that the District's existing SIP-approved emissions statement program under 20 DCMR section 500.9 satisfies the requirements of CAA section 182(a)(3)(B) for the 2015 ozone NAAQS.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 12, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

This action approving the District's emissions statement certification for the 2015 ozone NAAQS may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 5, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart J—District of Columbia

■ 2. In § 52.470, the table in paragraph (e) is amended by adding an entry for ''Emissions Statement Certification for the 2015 Ozone National Ambient Air Quality Standard'' at the end of the table to read as follows:

§ 52.470 Identification of plan.

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
* *	* *	*	*	* *
Emissions Statement Certification for the 2015 Ozone National Ambient Air Quality Standard.	The District of Columbia portion of the Washington, DC-MD-VA nonattainment area for the 2015 ozone NAAQS (*i.e.,* the District of Columbia.	6/4/20	8/13/21, [insert **Federal Register** citation].	Certification that the District's previously SIP-approved regulations at 20 DCMR section 500.9 meet the emissions statement requirements of CAA section 182(a)(3)(B) for the 2015 ozone NAAQS.

[FR Doc. 2021–17288 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2019–0031; FRL–8822–02–R5]

Air Plan Approval; Illinois; 2008 Ozone Moderate VOC RACT for Chicago

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving volatile organic compound (VOC) reasonably available control technology (RACT) State Implementation Plan (SIP) revisions for the Illinois portion of the Chicago-Naperville, IL–IN–WI nonattainment area (Illinois portion) under the 2008 8-hour ozone National Ambient Air Quality Standard (''NAAQS'' or ''standard'') submitted by the Illinois Environmental Protection Agency (''Illinois'' or ''Illinois EPA'') on January 10, 2019 and supplemented on April 30, 2020. EPA is also approving the Stepan Co. construction permit submitted by Illinois on March 29, 2021 as a revision to the Illinois SIP. The Illinois portion consists of Cook, DuPage, Kane, Lake, McHenry, and Will Counties and portions of Grundy (Aux Sable and Goose Lake Townships) and Kendall (Oswego Township) Counties. These VOC RACT SIP submittals satisfy the moderate VOC RACT requirements of section 182(b)(2) of the Clean Air Act (CAA). EPA proposed to approve this action on May 7, 2021 and received no comments.

DATES: This final rule is effective on September 13, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2019–0031. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through *www.regulations.gov* or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19. We recommend that you telephone Katie Mullen, Environmental Engineer, at (312) 353–3490 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Katie Mullen, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–3490, *Mullen.Kathleen@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. Background Information

On May 7, 2021, EPA proposed to approve VOC RACT SIP revisions for the Illinois portion (86 FR 24569). An explanation of the CAA requirements, a detailed analysis of the revisions, and EPA's reasons for proposing approval were provided in the notice of proposed rulemaking and will not be restated here. The public comment period for the proposed rule ended on June 7, 2021. EPA received no comments on the proposal.

II. Final Action

EPA is approving negative declarations, a VOC RACT certification, and the Stepan Co. construction permit submitted by Illinois as meeting the CAA section 182(b)(2) moderate RACT requirements for the Illinois portion under the 2008 8-hour ozone NAAQS.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference the Illinois Source-Specific Requirements described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov,* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be

incorporated by reference in the next update to the SIP compilation.[1]

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 12, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2) of the CAA.)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Volatile organic compounds.

Dated: July 30, 2021.

Cheryl Newton,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.720, the table in paragraph (d) is amended by adding an entry for ''Stepan Company Millsdale Plant'' after the entry for ''Solar Corporation, Libertyville, IL'' to read as follows:

§ 52.720 Identification of plan.

* * * * *

(d) * * *

EPA APPROVED—ILLINOIS SOURCE-SPECIFIC REQUIREMENTS

Name of source	Order/permit No.	State effective date	EPA approval date	Comments
*	*	*	*	*
Stepan Company Millsdale Plant	197800AAE	10/30/2020	8/13/2021, [INSERT **Federal Register** CITATION].	
*	*	*	*	*

* * * * *

[FR Doc. 2021–16883 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

[1] 62 FR 27968 (May 22, 1997).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0066; FRL–8671–01–OCSPP]

Emamectin benzoate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of emamectin benzoate in or on soybean, seed. Syngenta Crop Protection, LLC, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2021. Objections and requests for hearings must be received on or before October 12, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0066, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0066 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 12, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2019–0387, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 22, 2021 (86 FR 15162) (FRL–10021–44), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8817) by Syngenta Crop Protection, LLC, 410 Swing Road, Greensboro, NC 27409. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of insecticide emamectin benzoate (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B1a and a maximum of 10% 4′-epi-methylamino-4′deoxyavermectin B1b benzoate), and its metabolites 8,9 isomer of the B1a and B1b component of the parent insecticide in or on soybean, seed at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *https://www.regulations.gov/docket/EPA-HQ-OPP-2021-0066.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure

of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

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

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

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

Toxicological profile. The Toxicological Profile of emamectin remains unchanged from the Toxicological Profile in Unit III.A. of the August 27, 2019 rulemaking (84 FR 44718) (FRL–9997–10). Refer to that section for a discussion of the Toxicological Profile of emamectin.

Toxicological points of departure/Levels of concern. The Toxicological Points of Departure/Levels of Concern used for the safety assessment remain unchanged from Unit III.B. of the August 27, 2019 rulemaking. For a summary, refer to that discussion.

Exposure assessment. Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerance. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III. C. of the August 27, 2019 rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new use of emamectin on soybean, seed. All other assumptions in the exposure assessments for emamectin remain the same as in the August 27, 2019 rulemaking.

Drinking water and non-occupational exposures. Drinking water exposures and residential (non-occupational) exposures are not impacted by the new use, and thus have not changed since the last assessment.

There are no proposed residential uses of emamectin that would result in residential exposures. As a result, there are no residential risk estimates recommended for use in the aggregate risk assessment for emamectin.

Cumulative exposures. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' For the new uses of emamectin, the quantitative exposures to residues of emamectin remain unchanged, and the cumulative exposures remain identical to those as assessed within the 2021 cumulative assessment. There are no risks of concern resulting from these cumulative exposures.

Safety factor for infants and children. The scientific information underpinning EPA's prior safety factor determination remains unchanged from the August 27, 2019 rulemaking. EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the August 27, 2019 rulemaking for a discussion of the Agency's rationale for that determination.

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

Acute dietary risks are below the Agency's level of concern: 30% of the acute population adjusted dose (aPAD) for children 1 to 2 years old, the population group of concern. Chronic dietary risks are below the Agency's level of concern: 3.8% of the chronic population adjusted dose (cPAD) for children 1 to 2 years old, the group with the highest exposure. Emamectin is classified as ''Not likely to be Carcinogenic to Humans'', therefore, a cancer dietary exposure analysis was not performed.

There are no registered uses of emamectin that would result in residential exposure; therefore, aggregate exposure and risk estimates are equivalent to the dietary exposure and risk estimates and are not of concern. Using the exposure assumptions described for acute and chronic exposures, EPA has concluded the combined dermal and inhalation exposures result in aggregate margins of exposures for handler scenarios ranging from 200 to 27,000 and post-application scenarios ranging from 48,000 to 750,000, which are not of concern because they exceed EPA's level of concern (MOEs less than or equal to 100).

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to emamectin residues. More detailed information about the Agency's analysis can be found at *http://www.regulations.gov* in the document titled ''Emamectin Benzoate; Human Health Risk Assessment for a Proposed New Use on Soybean'' in docket ID number EPA–HQ–OPP–2021–0066.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the August 27, 2019 rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex has not established MRLs for residues of emamectin on soybeans.

V. Conclusion

Therefore, tolerances are established for residues of emamectin benzoate (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B1a and a maximum of 10% 4′-epi-methlyamino-4′deoxyavermectin B1b benzoate) and its metabolites in or on in or on the soybean, seed at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 29, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

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

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

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

■ 2. In § 180.505, add alphabetically the entry ''Soybean, seed'' to table 1 to paragraph (a)(1) to read as follows:

§ 180.505 Emamectin; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Soybean, seed	0.01
* * * * *	

* * * * *

[FR Doc. 2021–17184 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0450; FRL–8672–01–OCSPP]

Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro-; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- when used as an inert ingredient (dye, coloring agent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance for pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro-. This regulation eliminates the need to establish a maximum permissible level for residues of pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- when used in accordance with this exemption.

DATES: This regulation is effective August 13, 2021. Objections and requests for hearings must be received on or before October 12, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2020–0450, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William

Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0450 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 12, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0450, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of December 21, 2020 (85 FR 82998) (FRL–10016–93), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11384) by Spring Regulatory Sciences, on behalf of BASF Corporation, 100 Park Avenue, Florham Park, New Jersey 07932. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- (CAS Reg. No. 84632–65–5) when used as an inert ingredient (dye, coloring agent) in pesticide formulations applied pre- and post-harvest. That document referenced a summary of the petition prepared by BASF Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit V.B.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that EPA has determined that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but it does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to

determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure to pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- (also referred to as Pigment Red 254) as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Available acute toxicity studies on Pigment Red 254 show low oral, dermal, and inhalation toxicity. An eye irritation, a dermal irritation, and a dermal sensitization study were also available and showed no effect of treatment. No adverse effects of treatment were seen in rats in either a 28-day oral toxicity study or a reproduction/developmental toxicity study at the highest dose tested (1,000 mg/kg/day). Therefore, the NOAEL for the 28-day study and the parental, reproductive, and developmental NOAELs are (1,000 mg/kg/day).

There was no evidence of carcinogenicity or neuropathological changes or effects reported in any of the studies. There were no *in vivo* or *in vitro* mutagenic effects in mutagenicity testing with Pigment Red 254. The agency does not believe Pigment Red 254 will be carcinogenic or neurotoxic.

B. Toxicological Points of Departure/ Levels of Concern

No toxicological endpoint of concern for Pigment Red 254 has been identified in the database.

C. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water.* In evaluating dietary exposure to Pigment Red 254, EPA considered exposure under the current and proposed uses of Pigment Red 254. Dietary exposure to Pigment Red 254 may occur from eating foods treated with pesticide formulations containing this inert ingredient and drinking water containing runoff from soils containing the treated crops. In addition, Pigment Red 254 is used as an indirect food additive. However, no toxicological endpoint of concern was identified for Pigment Red 254, and therefore, a quantitative assessment of dietary exposure is not necessary.

2. *Non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Residential exposure to Pigment Red 254 may occur based on its use as an inert ingredient in pesticide formulations registered for residential uses. Additional non-dietary exposure may occur from use of Pigment Red 254 in consumer products. However, no toxicological endpoint of concern was identified for Pigment Red 254, and therefore, a quantitative residential exposure assessment for Pigment Red 254 was not conducted.

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

EPA has not found Pigment Red 254 to share a common mechanism of toxicity with any other substances, and Pigment Red 254 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has assumed that Pigment Red 254 does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of the FFDCA requires EPA to retain an additional tenfold margin of safety in the case of threshold effects to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. As noted in Unit IV.B., there is no indication of threshold effects being caused by Pigment Red 254. Therefore, this requirement does not apply to the present analysis. Moreover, due to the lack of any toxicological endpoints of concern, EPA conducted a qualitative assessment of Pigment Red 254, which does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on Pigment Red 254, EPA has determined that there is a reasonable certainty that no harm to the general population or any population subgroup, including infants and children, will result from aggregate exposure to Pigment Red 254 residues. Therefore, the establishment of exemptions from the requirement of a tolerance under 40 CFR 180.910 for residues of Pigment Red 254 when used as an inert ingredient in pesticide formulations pre- and post- harvest is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Response to Comments

One comment was received which asserted that Pigment Red 254 contains chlorine gas and opposed its use; however, chlorine gas is not a constituent nor a metabolite/degradate of Pigment Red 254 and is therefore not relevant to the assessment of this chemical.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- (CAS Reg. No. 84632–65–5) when used as an inert ingredient (dye, coloring agent) in pesticide formulations applied pre- and post-harvest.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 23, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

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

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

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

■ 2. In § 180.910, amend the table by adding in alphabetical order the inert ingredient ''Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- (CAS Reg. No. 84632–65–5)'' to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits	Uses
* * * * *	*	*
Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- (CAS Reg. No. 84632–65–5)	.....	Dye, coloring agent.
* * * * *	*	*

[FR Doc. 2021–17192 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0050; FRL–8560–01–OCSPP]

Boscalid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of boscalid in or on tea, dried; tea, instant. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2021. Objections and requests for hearings must be received

on or before October 12, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2020–0050, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0050 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 12, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0050, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 30, 2020 (85 FR 61681) (FRL–10014–74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8819) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.589 be amended by establishing tolerances for residues of the fungicide boscalid in or on tea at 80 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* No comments were received in response to the notice of filing.

FFDCA section 408(d)(4)(A)(i) permits the Agency to finalize a tolerance that varies from that sought by the petition. Based upon review of the data supporting the petition, EPA has modified the tolerance level being established and corrected the commodity definition of ''tea'' to ''tea, dried'' and ''tea, instant.'' The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

A. Statutory Background

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

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

B. Aggregate Risk Assessment

In an effort to streamline **Federal Register** publications, EPA is not

reprinting sections that have not changed from previous rulemakings for the same pesticide. On October 19, 2018, EPA published in the **Federal Register** a final rule establishing tolerances for residues of boscalid in or on multiple commodities based on the Agency's conclusion that aggregate exposure to boscalid is safe for the general population, including infants and children. *See* 83 FR 52991 (EPA–HQ–OPP–2017–0310). Refer to the following sections from the previous tolerance rulemaking for boscalid that have remained the same under the current risk assessment: Units III.A (Toxicological Profile); III.B (Toxicological Points of Departure/Levels of Concern); III.C. (Exposure Assessment), except as explained below; and III.D. (Safety Factor for Infants and Children). EPA has conducted an updated human health risk assessment to evaluate the safety of the requested tolerances, which is limited to an updated dietary exposure and risk assessment, and subsequent updates to the aggregate exposure and risk assessment. *See* ''Boscalid. Human Health Risk Assessment for the Establishment of a Permanent Tolerance Without a U.S. Registration on Tea.'' (D456100, 04/01/2021), which is available in the docket established by this action, EPA–HQ–OPP–2020–0050.

Updates to exposure assessment. EPA's dietary (food and drinking water) exposure assessments have been updated to include the potential additional exposure from the tolerance for boscalid residues in or on tea, dried and tea, instant. The exposure assessments relied on tolerance-level residues for all crops and an assumption of 100 percent crop treated (PCT) as the October 19, 2018, final rule. Exposure in drinking water and from residential sources are not impacted by the increased tolerance on tea, dried and tea, instant because the tolerances are without U.S. registration.

Assessment of aggregate risks. An acute dietary exposure assessment was not conducted because there were no observed effects attributable to a single dose. Chronic dietary risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD): 60% of the cPAD for children 1 to 2 years old, the most highly exposed population subgroup.

For the aggregate risk assessment, exposures to boscalid in food and drinking water are combined with residential exposures for the relevant exposure duration period. There is potential for short-term aggregate exposure to boscalid via dietary (which is considered background exposure) and residential (which is considered primary) exposure pathways. The short-term aggregate margins of exposure (MOEs) are 160 for children 6 to 11 years old, 360 for youth 11 to 16 years old, and 130 for adults (LOC = 100), which are not of concern because they exceed EPA's level of concern (MOEs less than or equal to 100).

A separate cancer dietary assessment was not conducted since boscalid was classified by the Cancer Assessment Review Committee (CARC) as ''suggestive evidence of carcinogenicity''; and the chronic exposure assessment is protective of any cancer risks. Therefore, based on the chronic exposure assessment, which accounts for potential carcinogenicity, EPA does not expect boscalid to pose a cancer risk.

C. Determination of Safety

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to boscalid residues. More detailed information about the Agency's analysis can be found in the document entitled, ''Boscalid. Human Health Risk Assessment for the Establishment of a Permanent Tolerance Without a U.S. Registration on Tea.'' (D456100, 04/01/2021) by going to *http://www.regulations.gov.*

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methods exist for both plants and livestock. In plants, the parent residue is extracted using an aqueous organic solvent mixture followed by liquid/liquid partitioning and a column clean up. Quantitation is by gas chromatography using mass spectrometry (GC/MS) or liquid chromatography in tandem with mass spectrometric detection (LC/MS/MS). In livestock, the residues are extracted with methanol. The extract is treated with enzymes in order to release the conjugated glucuronic acid metabolite. The residues are then isolated by liquid/liquid partition followed by column chromatography. The hydroxylated metabolite is acetylated followed by a column clean-up. The parent and acetylated metabolite are quantitated by gas chromatography with electron capture detection.

Adequate enforcement methodology, extraction using an aqueous organic solvent mixture followed by liquid/liquid partitioning and a column clean up with quantitation by gas chromatography using mass spectrometry (GC/MS) or liquid chromatography in tandem with mass spectrometric detection (LC/MS/MS), is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for boscalid. Taiwan has an MRL for residues of boscalid in/on dried tea leaves at 10 ppm, and Japan has an MRL of residues of boscalid in/on dried tea leaves at 60 ppm. The tolerance expression for Taiwan and Japan are harmonized with the US tolerance definition in crops as parent boscalid only but do not metabolites and degradates. All international MRLs fall below the calculated tolerance value of 70 ppm.

C. Revisions to Petitioned-For Tolerances

The petitioned-for tolerance for residues on the commodity tea at 80 ppm is revised so that there will be two separate tolerances for residues on tea, dried and tea, instant each at 70 ppm and corrected commodity definitions. The tolerance is also revised pursuant to a difference in how the tolerances are calculated. The registrant calculated a processing factor for dried black tea as 4.1x and used the field trial values from the fresh leaves at 7-days. EPA determined the processing factor to be no greater than 2.54x and extrapolated the 7-day residues for black tea based on the combination of the processing factor and the decline trend for fresh leaves.

V. Conclusion

Therefore, tolerances are established for residues of boscalid, in or on Tea, dried; and Tea, instant at 70 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 2, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

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

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

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

■ 2. In § 180.589 amend the table in paragraph (a)(1) by adding in alphabetical order entries for ''Tea, dried[2]'' and ''Tea, instant [2]'' to read as follows:

§ 180.589 Boscalid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Tea, dried[2]	70
Tea, instant[2]	70
* * * * *	

[2] There are no U.S. registrations for these commodities as of August 13, 2021.

* * * * *

[FR Doc. 2021–16973 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

National Endowment for the Humanities

45 CFR Part 1174

RIN 3136–AA36

Implementation of the Program Fraud Civil Remedies Act of 1986

AGENCY: National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

ACTION: Final rule.

SUMMARY: The National Endowment for the Humanities (NEH) is adopting as final its proposed regulations to implement the Program Fraud Civil Remedies Act of 1986 (PFCRA). The PFCRA authorizes certain Federal agencies, including NEH, to impose civil penalties and assessments through administrative adjudication against any person who makes, submits, or presents a false, fictitious, or fraudulent claim or written statement to NEH. The rule establishes the procedures that NEH will follow in implementing the PFCRA, and specifies the hearing and appeal rights of persons subject to penalties and assessments under the PFCRA.

DATES: This final rule is effective on August 13, 2021.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Deputy General Counsel, Office of the General Counsel, National Endowment for the Humanities, 400 7th Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *gencounsel@neh.gov.*

SUPPLEMENTARY INFORMATION:

1. Background

On June 25, 2021, NEH published in the **Federal Register** a notice of proposed rulemaking (86 FR 33603), requesting public comment on a proposed rule to implement to implement the PFCRA. The agency received no comments. Accordingly, NEH is adopting the rule as proposed, subject to certain minor corrections to the rule's organization and formatting.

In October 1986, Congress enacted the PFCRA, 31 U.S.C. 3801–3812. The PFCRA established an administrative remedy against any person who makes, or causes to be made, a false claim or written statement to certain Federal agencies. The PFCRA requires these

Federal agencies to follow certain procedures in recovering penalties and assessments against people who file false claims or statements for which the liability is $150,000 or less. Initially, the PFCRA did not apply to NEH. Section 10 of the Inspector General Reform Act of 2008, Public Law 110–409, 122 Stat. 4314, however, expanded the PFCRA's scope to include NEH.

The PFCRA requires each covered agency to promulgate rules and regulations necessary to implement its provisions. Following the PFCRA's enactment, the President's Council on Integrity and Efficiency requested that the Department of Health and Human Services lead an inter-agency task force to develop model PFCRA regulations. This action was in keeping with the Senate Governmental Affairs Committee's desire that ''the regulations would be substantially similar throughout the government'' (S. Rep. No. 99–212, 99th Cong., 1st Sess. 12 (1985)). The Council recommended that all covered agencies adopt the model rule.

Accordingly, NEH is implementing the PFCRA's provisions through this final rule—which substantively conforms to the model rule—in order to establish procedures by which NEH will seek to recover penalties and assessments against persons who file, or cause to have filed, false claims or statements with NEH for which liability is $150,000 or less.

2. Maximum Penalty Amount

The PFCRA established a maximum penalty of $5,000 for each violation. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), 28 U.S.C. 2461 note, required all Federal agencies to (1) adjust the penalty amount to 2016 inflation levels with an initial ''catch-up'' inflation adjustment; and (2) make subsequent annual adjustments for inflation.[1] This rule incorporates the initial ''catch-up'' adjustment to 2016 inflation levels and the annual adjustments for 2017 through 2021, and applies those adjustments cumulatively to the civil monetary penalties that the PFCRA imposes.[2]

A. Initial ''Catch-Up'' and 2021 Adjustments for Inflation

NEH determined the first ''catch-up'' adjustment to 2016 inflation levels using the formula set forth in the 2015 Act. Specifically, NEH calculated the percent change between the Consumer Price Index for all Urban Consumers (CPI–U) for October of the last year in which Congress adjusted the PFCRA civil penalties (October 1986) and the CPI–U for October 2015, and then rounded to the nearest dollar.

NEH similarly determined each subsequent annual adjustment by calculating the percent increase between the CPI–U for the month of October preceding the date of the adjustment and the CPI–U for the October one year prior to the October immediately preceding the date of the adjustment.

Table 1, below, details the above calculations.

TABLE 1—ANNUAL ADJUSTMENTS TO PFCRA CIVIL MONETARY PENALTIES, 2016–2021

Effective date	Baseline maximum penalty	Applicable multiplier based on percent increase in CPI–U	New baseline maximum penalty
August 1, 2016	$5,000	[3] 2.15628	$10,781
January 15, 2017	10,781	[4] 1.01636	10,957
January 15, 2018	10,957	[5] 1.02041	11,181
January 15, 2019	11,181	[6] 1.02522	11,463
January 15, 2020	11,463	[7] 1.01764	11,665
January 15, 2021	11,665	[8] 1.01182	11,803

B. Future Annual Adjustments

The 2015 Act requires agencies to make annual adjustments to civil penalty amounts no later than January 15 of each year following the initial adjustment. NEH will calculate future annual adjustments using the same method as the adjustments previously described herein. If the CPI–U does not increase, then the civil penalties remain the same.

NEH will publish a Notice in the **Federal Register** containing the amount of these annual inflation adjustments no later than January 15 of each year.

Executive Order 12866, Regulatory Planning and Review, and Executive Order 13563, Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget for review.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 12988, Civil Justice Reform

This rulemaking meets the applicable standards set forth in section 3(a) and 3(b)(2) of Executive Order 12988. Specifically, this rulemaking is written in clear language designed to help reduce litigation.

Executive Order 13175, Indian Tribal Governments

Under the criteria in Executive Order 13175, NEH evaluated this rulemaking and determined that it will not have any

[1] For a more detailed explanation of the 2015 Act and the civil monetary penalty inflation adjustment calculations that it requires, see NEH's regulation implementing the 2015 Act at 85 FR 35566.

[2] Table 1 details the annual adjustments to the PFCRA maximum penalty amount for years 2016–2021.

[3] Office of Management and Budget, Memorandum M–16–06 (February 24, 2016).

[4] Office of Management and Budget, Memorandum M–17–11 (December 16, 2016).

[5] Office of Management and Budget, Memorandum M–18–03 (December 15, 2017).

[6] Office of Management and Budget, Memorandum M–19–04 (December 14, 2018).

[7] Office of Management and Budget, Memorandum M–20–05 (December 16, 2019).

[8] Office of Management and Budget, Memorandum M–21–10 (December 23, 2020).

potential effects on Federally recognized Indian Tribes.

Executive Order 12630, Takings

Under the criteria in Executive Order 12630, this rulemaking does not have significant takings implications. Therefore, a takings implication assessment is not required.

Regulatory Flexibility Act of 1980

This rulemaking will not have a significant adverse impact on a substantial number of small entities, including small businesses, small governmental jurisdictions, or certain small not-for-profit organizations.

Paperwork Reduction Act of 1995

This rulemaking does not impose an information collection burden under the Paperwork Reduction Act. This action contains no provisions constituting a collection of information pursuant to the Paperwork Reduction Act.

Unfunded Mandates Reform Act of 1995

This rulemaking does not contain a Federal mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year.

National Environmental Policy Act of 1969

This rulemaking will not have a significant effect on the human environment.

Small Business Regulatory Enforcement Fairness Act of 1996

This rulemaking will not be a major rule as defined in section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rulemaking will not result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

E-Government Act of 2002

All information about NEH required to be published in the **Federal Register** may be accessed at *www.neh.gov.* The website *www.regulations.gov* contains electronic dockets for NEH's rulemakings under the Administrative Procedure Act of 1946.

Plain Writing Act of 2010

To ensure this rule speaks in plain and clear language so that the public can use and understand it, NEH modeled the language of the rule on the Federal Plain Language Guidelines.

List of Subjects in 45 CFR 1174

Claims, Fraud, Penalties.

For the reasons set forth in the preamble, the National Endowment for the Humanities amends 45 CFR chapter XI by adding part 1174 to read as follows:

PART 1174—PROGRAM FRAUD CIVIL REMEDIES ACT REGULATIONS

Subpart A—Purpose, Definitions, and Basis for Liability

Sec.

1174.1 Purpose.
1174.2 Definitions.
1174.3 Basis for civil penalties and assessments.

Subpart B—Procedures Leading to Issuance of a Complaint

1174.4 Who investigates program fraud.
1174.5 Review of suspected program fraud by the reviewing official.
1174.6 Prerequisites for issuing a complaint.
1174.7 Contents of a complaint.
1174.8 Service of a complaint.

Subpart C—Procedures Following Service of a Complaint

1174.9 Answer to a complaint.
1174.10 Default upon failure to file an answer.
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1174.12 Notice of hearing.
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1174.22 Exchange of witness lists, statements, and exhibits.
1174.23 Subpoenas for attendance at the hearing.
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1174.25 Filing and serving documents with the ALJ.
1174.26 Computation of time.
1174.27 The hearing and the burden of proof.
1174.28 Presentation of evidence.
1174.29 Witness testimony.
1174.30 Ex parte communications.
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Subpart E—Decisions and Appeals

1174.33 Initial decision.
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1174.35 Reconsideration of the initial decision.
1174.36 Finalizing the initial decision.
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1174.41 Rights to administrative offset.
1174.42 Deposit in Treasury of the United States.
1174.43 Voluntary settlement of the administrative complaint.
1174.44 Limitations regarding criminal misconduct.

Authority: 31 U.S.C. 3801–3812; 5 U.S.C. App. 8G(a)(2).

Subpart A—Purpose, Definitions, and Basis for Liability

§ 1174.1 Purpose.

This part implements the Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801–3812 (PFCRA). The PFCRA provides the National Endowment for the Humanities (NEH), and other Federal agencies, with an administrative remedy to impose civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted or presented, false, fictitious, or fraudulent claims or written statements to NEH. The PFCRA also provides due process protections to all persons who are subject to administrative proceedings under this part.

§ 1174.2 Definitions.

For the purposes of this part—

ALJ means an Administrative Law Judge in the authority appointed pursuant to 5 U.S.C. 3105 or detailed to the authority pursuant to 5 U.S.C. 3344.

Authority means the National Endowment for the Humanities (NEH).

Authority head means the NEH Chairperson or the Chairperson's designee.

Benefit means anything of value, including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status or loan guarantee.

Claim means any request, demand or submission that a person makes—

(1) To the authority—

(i) For property, services, or money (including money representing grants, loans, insurance, or benefits); or

(ii) Which has the effect of decreasing an obligation to pay or account for property, services, or money; or

(2) To a recipient of property, services, or money from the authority or to a party to a contract with the authority—

(i) For property or services if the United States—

(A) Provided such property or services;

(B) Provided any portion of the funds for the purchase of such property or services; or

(C) Will reimburse such recipient or party for the purchase of such property or services; or

(ii) For the payment of money (including money representing grants, loans, insurance, or benefits) if the United States—

(A) Provided any portion of the money requested or demanded; or

(B) Will reimburse such recipient or party for any portion of the money paid on such request or demand.

Complaint means the administrative complaint that the reviewing official serves on the defendant under § 1174.8.

Defendant means any person alleged in a complaint to be liable for a civil penalty or assessment pursuant to the PFCRA.

Government means the United States Government.

Individual means a natural person.

Initial decision means the written decision of the ALJ under § 1174.33, and includes a revised initial decision issued following a remand or a motion for reconsideration.

Knows or has reason to know means that a person, with respect to a claim or statement—

(1) Has actual knowledge that the claim or statement is false, fictitious, or fraudulent;

(2) Acts in deliberate ignorance of the truth or falsity of the claim or statement; or

(3) Acts in reckless disregard of the truth or falsity of the claim or statement;

and no proof of specific intent to defraud is required.

Makes shall include the terms presents, submits, and causes to be made, presented, or submitted. As the context requires, making or made shall likewise include the corresponding forms of such terms.

Person means any individual, partnership, corporation, association, or private organization, and includes the plural of that term.

Representative means an attorney who is in good standing of the bar of any State, Territory, or possession of the United States, or the District of Columbia, or the Commonwealth of Puerto Rico, or any other individual who the defendant designates in writing.

Reviewing official means the NEH General Counsel or the General Counsel's designee.

Statement means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry that a person makes—

(1) With respect to a claim (or eligibility to make a claim) or to obtain the approval or payment of a claim; or

(2) With respect to (or with respect to eligibility for)—

(i) A contract with, or a bid or proposal for a contract with, or

(ii) A grant, loan, or benefit from, the authority, or any State, political subdivision of a State, or other party, if the United States Government provides any portion of the money or property under such contract or for such grant, loan, or benefit, or if the Government will reimburse such State, political subdivision, or party for any portion of the money or property under such contract or for such grant, loan, or benefit.

§ 1174.3 Basis for civil penalties and assessments.

(a) *Claims.* (1) Any person shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than $11,803 for each claim that person makes that the person knows or has reason to know—

(i) Is false, fictitious, or fraudulent;

(ii) Includes or is supported by any written statement which asserts a material fact which is false, fictitious, or fraudulent;

(iii) Includes or is supported by any written statement that—

(A) Omits a material fact;

(B) Is false, fictitious, or fraudulent as a result of such omission; and

(C) Is a statement in which the person making such statement has a duty to include such material fact; or

(iv) Is for payment for the provision of property or services which the person has not provided as claimed.

(2) Each voucher, invoice, claim form, or other individual request or demand for property, services, or money constitutes a separate claim.

(3) A claim shall be considered made to the authority, recipient, or party when such a claim is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision of a State, acting for or on behalf of the authority.

(4) Each claim for property, services, or money is subject to a civil penalty regardless of whether such property, services, or money is actually delivered or paid.

(5) If the Government has made any payment on a claim, a person subject to a civil penalty under paragraph (a)(1) of this section may also be subject to an assessment of not more than twice the amount of that claim or the portion thereof that violates paragraph (a)(1) of this section. Such assessment shall be in lieu of damages that the Government sustained because of such a claim.

(b) *Statements.* (1) Any person shall be subject, in addition to any other remedy prescribed by law, to a civil penalty of not more than $11,803 for each written statement that person makes that the person knows or has reason to know—

(i) Asserts a material fact which is false, fictitious or fraudulent; or

(ii) Is false, fictitious, or fraudulent because it omits a material fact that the person making the statement has a duty to include in such a statement; and

(iii) Contains or is accompanied by an express certification or affirmation of the truthfulness and accuracy of the statement's contents.

(2) A person will only be subject to a civil penalty under paragraph (b)(1) of this section if the written statement made by the person contains or is accompanied by an express certification or affirmation of the truthfulness and accuracy of the statement's contents.

(3) Each written representation, certification, or affirmation constitutes a separate statement.

(4) A statement shall be considered made to the authority when it is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision of a State, acting for or on behalf of the authority.

(c) Proof of specific intent to defraud is not required to establish liability under this section.

(d) In any case in which more than one person is liable for making a false, fictitious, or fraudulent claim or statement under this section, each person may be held liable for a civil penalty and assessment.

(e) In any case in which more than one person is liable for making a claim under this section on which the Government has made payment, the authority may impose an assessment against any such person or jointly and severally against any combination of persons.

(f) The authority will annually adjust for inflation the maximum amount of the civil penalties described in this section, and will publish a document in the **Federal Register** containing the new maximum amount no later than January 15 of each year.

Subpart B—Procedures Leading to Issuance of a Complaint

§ 1174.4 Who investigates program fraud.

The Inspector General, or his or her designee, is the investigating official responsible for investigating allegations that a person has made a false claim or statement. In this regard, the Inspector General has authority under the PFCRA and the Inspector General Act of 1978,

5 U.S.C. App. 3, as amended, to issue administrative subpoenas for the production of records and documents.

§ 1174.5 Review of suspected program fraud by the reviewing official.

(a) If the investigating official concludes that the results of his or her investigation warrant an action under this part, the investigating official shall submit to the reviewing official a report containing the investigation's findings and conclusions.

(b) If the reviewing official determines that the report provides adequate evidence that a person made a false, fictitious or fraudulent claim or statement, the reviewing official shall transmit to the Attorney General written notice of the reviewing official's intention to refer the matter for adjudication, with a request for approval of such referral. This notice will include the reviewing official's statement concerning:

(1) The reasons for the referral;

(2) The claims or statements that form the basis for liability;

(3) The evidence that supports liability;

(4) An estimate of the amount of money or the value of property, services, or other benefits requested or demanded in the false claim or statement;

(5) Any exculpatory or mitigating circumstances that may relate to the claims or statements that are known by the reviewing official or the investigating official; and

(6) A statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments.

(c) If, at any time, the Attorney General (or designee) requests in writing that the authority stay this administrative process, the authority head must stay the process immediately. The authority head may resume the process only upon receipt of the Attorney General's written authorization.

§ 1174.6 Prerequisites for issuing a complaint.

The authority may issue a complaint only if:

(a) The Attorney General (or designee) approves the reviewing official's referral of the allegations for adjudication; and

(b) In a case of submission of false claims, if the amount of money or the value of property or services that a false claim (or a group of related claims submitted at the same time) demanded or requested does not exceed $150,000.

§ 1174.7 Contents of a complaint.

(a) The complaint will state that the authority seeks to impose civil penalties, assessments, or both, against the defendant and will include:

(1) The allegations of liability against the defendant and the statutory basis for liability, identification of the claims or statements involved, and the reasons liability allegedly arises from such claims or statements;

(2) The maximum amount of penalties and assessments for which the defendant may be held liable;

(3) A statement that the defendant may request a hearing by filing an answer and may be represented by a representative;

(4) Instructions for filing such an answer; and

(5) A warning that failure to file an answer within thirty days of service of the complaint will result in an imposition of the maximum amount of penalties and assessments.

(b) The reviewing official must serve the complaint on the defendant and, if the defendant requests a hearing, provide a copy to the ALJ assigned to the case.

§ 1174.8 Service of a complaint.

(a) The reviewing official must serve the complaint on an individual defendant directly, on a partnership through a general partner, and on a corporation or an unincorporated association through an executive officer or a director, except that the reviewing official may also make service on any person authorized by appointment or by law to receive process for the defendant.

(b) The reviewing official may serve the complaint either by:

(1) Registered or certified mail; or

(2) Personal delivery by anyone eighteen years of age or older.

(c) The date of service is the date of personal delivery or, in the case of service by registered or certified mail, the date of postmark.

(d) When the reviewing official serves the complaint, he or she should also serve the defendant with a copy of this part and 31 U.S.C. 3801–3812.

Subpart C—Procedures Following Service of a Complaint

§ 1174.9 Answer to a complaint.

(a) A defendant may file an answer with the reviewing official within thirty days of service of the complaint. An answer will be considered a request for an oral hearing.

(b) In the answer, the defendant—

(1) Must admit or deny each allegation of liability contained in the complaint (a failure to deny an allegation is considered an admission);

(2) Must state any defense on which the defendant intends to rely;

(3) May state any reasons why the penalties, assessments, or both should be less than the statutory maximum; and

(4) Must state the name, address, and telephone number of the person the defendant authorized to act as the defendant's representative, if any.

(c) If the defendant is unable to file a timely answer which meets the requirements set forth in paragraph (b) of this section, the defendant may file with the reviewing official a general answer denying liability, requesting a hearing, and requesting an extension of time in which to file a complete answer. The defendant must file a general answer within thirty days of service of the complaint.

(d) If the defendant initially files a general answer requesting an extension of time, the reviewing official must promptly file with the ALJ the complaint, the general answer, and the request for an extension of time.

(e) For good cause shown, the ALJ may grant the defendant up to thirty additional days within which to file an answer that meets the requirements of paragraph (b) of this section. The defendant must file such an answer with the ALJ and must serve a copy on the reviewing official.

§ 1174.10 Default upon failure to file an answer.

(a) If the defendant does not file any answer within thirty days after service of the complaint, the reviewing official may refer the complaint to the ALJ.

(b) Once the reviewing official refers the complaint, the ALJ will promptly serve on the defendant a notice that the ALJ will issue an initial decision.

(c) The ALJ will assume the facts alleged in the complaint to be true and, if such facts establish liability under the statute, the ALJ will issue an initial decision imposing the maximum amount of penalties and assessments allowed under the PFCRA.

(d) Except as otherwise provided in this section, when a defendant fails to file a timely answer, the defendant waives any right to further review of the penalties and assessments the ALJ may impose in the initial decision.

(e) The initial decision becomes final thirty days after the ALJ issues it.

(f) At any time before an initial decision becomes final, a defendant may file a motion with the ALJ asking that the ALJ reopen the case. An ALJ may only reopen a case if he or she determines that the defendant set forth in the motion extraordinary circumstances that prevented the defendant from filing a timely answer.

The initial decision will be stayed until the ALJ decides on the motion. The reviewing official may respond to the motion.

(g) If the ALJ determines that a defendant has demonstrated extraordinary circumstances that excuse his or her failure to file a timely answer, the ALJ will withdraw the initial decision and grant the defendant an opportunity to answer the complaint.

(h) The ALJ's decision to deny a defendant's motion to reopen a case is not subject to reconsideration under § 1174.35.

(i) The defendant may appeal the ALJ's decision denying a motion to reopen by filing a notice of appeal with the authority head within fifteen days after the ALJ denies the motion. The timely filing of a notice of appeal shall stay the initial decision until the authority head decides the issue.

(j) If the defendant files a timely notice of appeal with the authority head, the ALJ shall forward the record of the proceeding to the authority head.

(k) The authority head shall decide expeditiously, based solely on the record before the ALJ, whether extraordinary circumstances excuse the defendant's failure to file a timely answer.

(l) If the authority head decides that extraordinary circumstances excuse the defendant's failure to file a timely answer, the authority head shall remand the case to the ALJ with instructions to grant the defendant an opportunity to answer.

(m) If the authority head decides that the circumstances do not excuse the defendant's failure to file a timely answer, the authority head shall reinstate the ALJ's initial decision, which shall become final and binding upon the parties thirty days after the authority head issues such a decision.

§ 1174.11 Referral of complaint and answer to the ALJ.

When the reviewing official receives an answer, he or she must simultaneously file the complaint, the answer, and a designation of the authority's representative with the ALJ.

Subpart D—Hearing Procedures

§ 1174.12 Notice of hearing.

(a) When the ALJ receives the complaint and the answer, the ALJ will promptly serve a notice of hearing upon the defendant and the authority's representative in the same manner as the complaint. The ALJ must serve the notice of oral hearing within six years of the date on which the claim or statement was made.

(b) The hearing is a formal proceeding conducted by the ALJ during which a defendant will have the opportunity to cross-examine witnesses, present testimony, and dispute liability.

(c) The notice of hearing must include:

(1) The tentative date, time, and place of the hearing;

(2) The legal authority and jurisdiction under which the hearing is being held;

(3) The matters of fact and law to be asserted;

(4) A description of the procedures for the conduct of the hearing;

(5) The name, address, and telephone number of the defendant's representative and the representative for the authority; and

(6) Such other matters as the ALJ deems appropriate.

§ 1174.13 Location of the hearing.

(a) The ALJ shall hold the hearing:

(1) In any judicial district of the United States in which the defendant resides or transacts business;

(2) In any judicial district of the United States in which a claim or statement in issue was made; or

(3) In such other place as the parties and the ALJ may agree upon.

(b) Each party shall have the opportunity to present arguments with respect to the location of the hearing.

(c) The ALJ shall decide the time and the place of the hearing.

§ 1174.14 Parties to the hearing and their rights.

(a) The parties to the hearing shall be the defendant and the authority.

(b) Except where the authority head designates another representative, the NEH General Counsel (or designee) shall represent the authority.

(c) Each party has the right to:

(1) Be represented by a representative;

(2) Request a pre-hearing conference and participate in any conference held by the ALJ;

(3) Conduct discovery;

(4) Agree to stipulations of fact or law which will be made a part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present arguments at the hearing as permitted by the ALJ; and

(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing, as permitted by the ALJ.

§ 1174.15 Separation of functions.

(a) The investigating official, the reviewing official, and any employee or agent of the authority who takes part in investigating, preparing, or presenting a particular case may not, in such case or a factually related case:

(1) Participate in the hearing as the ALJ;

(2) Participate or advise in the authority head's review of the initial decision; or

(3) Make the collection of penalties and assessment.

(b) The ALJ must not be responsible to or subject to the supervision or direction of the investigating official or the reviewing official.

§ 1174.16 The ALJ's role and authority.

(a) An ALJ serves as the presiding officer at all hearings. The Office of Personnel Management selects the ALJ.

(b) The ALJ must conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(c) The ALJ has the authority to—

(1) Set and change the date, time, and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing, in whole or in part, for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring witness attendance and the production of documents at depositions or at hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery;

(8) Regulate the course of the hearing and the conduct of representatives and parties;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment when there is no disputed issue of material fact;

(13) Conduct any conference, argument or hearing on motions in person or by telephone; and

(14) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under this part.

(d) The ALJ does not have the authority to find Federal statutes or regulations invalid.

§ 1174.17 Disqualification of reviewing official or ALJ.

(a) A reviewing official or an ALJ may disqualify himself or herself at any time.

(b) Upon any party's motion, the reviewing official or ALJ may be disqualified as follows:

(1) The party must support the motion by an affidavit containing specific facts establishing that personal bias or other reason for disqualification exists, including the time and circumstances of the party's discovery of such facts;

(2) The party must file the motion promptly after discovery of the grounds for disqualification or the objection will be deemed waived; and

(3) The party, or representative of record, must certify in writing that such party makes the motion in good faith.

(c) Once a party has filed a motion to disqualify, the ALJ will halt the proceedings until he or she resolves the disqualification matter. If the ALJ disqualifies the reviewing official, the ALJ will dismiss the complaint without prejudice. If the ALJ disqualifies himself or herself, the authority will promptly reassign the case to another ALJ.

§ 1174.18 Parties' rights to review documents.

(a) Once the ALJ issues a hearing notice pursuant to § 1174.12, and upon written request to the reviewing official, the defendant may:

(1) Review any relevant and material documents, transcripts, records, and other materials that relate to the allegations set out in the complaint and upon which the investigating official based his or her findings and conclusions, unless such documents are subject to a privilege under Federal law, and obtain copies of such documents upon payment of duplication fees; and

(2) Obtain a copy of all exculpatory information in the reviewing official's or investigating official's possession that relates to the allegations in the complaint, even if it appears in a document that would otherwise be privileged. If the document would otherwise be privileged, the other party only must disclose the portion containing exculpatory information.

(b) The notice that the reviewing official sends to the Attorney General, as described in § 1174.5(b), is not discoverable under any circumstances.

(c) If the reviewing official does not respond to the defendant's request within twenty days, the defendant may file with the ALJ a motion to compel disclosure of the documents, subject to the provisions of this section. The defendant may only file such a motion with the ALJ after filing an answer pursuant to § 1174.9.

§ 1174.19 Discovery.

(a) Parties may conduct the following types of discovery:

(1) Requests for production of documents for inspection and copying;

(2) Requests for admissions of authenticity of any relevant document or of the truth of any relevant fact;

(3) Written interrogatories; and

(4) Depositions.

(b) For the purpose of this section, the term ''documents'' includes information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained herein shall be interpreted to require the creation of a document.

(c) Unless the parties mutually agree to discovery, a party may conduct discovery only as ordered by the ALJ. The ALJ shall regulate the timing of discovery.

(d) Each party shall bear its own discovery costs.

§ 1174.20 Discovery motions.

(a) Any party seeking discovery may file a motion with the ALJ together with a copy of the requested discovery, or in the case of depositions, a summary of the scope of the proposed deposition.

(b) Within ten days of service, a party may file an opposition to the motion and/or a motion for protective order as provided in § 1174.24.

(c) The ALJ may grant a motion for discovery only if he or she finds that the discovery sought—

(1) Is necessary for the expeditious, fair, and reasonable consideration of the issues;

(2) Is not unduly costly or burdensome;

(3) Will not unduly delay the proceeding; and

(4) Does not seek privileged information.

(d) The burden of showing that the ALJ should allow discovery is on the party seeking discovery.

(e) The ALJ may grant discovery subject to a protective order under § 1174.24.

§ 1174.21 Depositions.

(a) If the ALJ grants a motion for deposition, the ALJ shall issue a subpoena for the deponent, which may require the deponent to produce documents. The subpoena shall specify the time and place at which the deposition will take place.

(b) The party seeking to depose shall serve the subpoena in the manner prescribed by § 1174.8.

(c) The deponent may file with the ALJ a motion to quash the subpoena or a motion for a protective order within ten days of service.

(d) The party seeking to depose shall provide for the taking of a verbatim transcript of the deposition, which it shall make available to all other parties for inspection and copying.

§ 1174.22 Exchange of witness lists, statements, and exhibits.

(a) As ordered by the ALJ, the parties must exchange witness lists and copies of proposed hearing exhibits, including copies of any written statements or transcripts of deposition testimony that each party intends to offer in lieu of live testimony.

(b) If a party objects, the ALJ will not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to an opposing party in advance, unless the ALJ finds good cause for the omission or concludes that there is no prejudice to the objecting party.

(c) Unless a party objects within the time set by the ALJ, documents exchanged in accordance with this section are deemed to be authentic for the purpose of admissibility at the hearing.

§ 1174.23 Subpoenas for attendance at the hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may request that the ALJ issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request no less than fifteen days before the hearing date unless otherwise allowed by the ALJ for good cause shown. Such request shall specify any documents to be produced, designate the witness, and describe the witness' address and location with sufficient particularity to permit the witness to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the same manner prescribed in § 1174.8. The party seeking the subpoena may serve the subpoena on a party, or upon an individual under the control of a party, by first class mail.

(f) The party requesting a subpoena shall pay the subpoenaed witness' fees and mileage in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage shall accompany the subpoena when it is served, except that when the authority

issues a subpoena, a check for witness fees and mileage need not accompany the subpoena.

(g) A party, or the individual to whom the subpoena is directed, may file with the ALJ a motion to quash the subpoena within ten days after service, or on or before the time specified in the subpoena for compliance if it is less than ten days after service.

§ 1174.24 Protective orders.

(a) A party, prospective witness, or deponent may file a motion for a protective order that seeks to limit the availability or disclosure of evidence with respect to discovery sought by an opposing party or with respect to the hearing.

(b) In issuing a protective order, the ALJ may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

(1) That the parties shall not have discovery;

(2) That the parties shall have discovery only on specified terms and conditions;

(3) That the parties shall have discovery only through a method of discovery other than requested;

(4) That the parties shall not inquire into certain matters, or that the parties shall limit the scope of discovery to certain matters;

(5) That the parties shall conduct discovery with no one present except persons designated by the ALJ;

(6) That the parties shall seal the contents of the discovery;

(7) That a sealed deposition shall be opened only by order of the ALJ;

(8) That a trade secret or other confidential research, development, commercial information, or facts pertaining to any criminal investigation, proceeding, or other administrative investigation shall not be disclosed or shall be disclosed only in a designated way; or

(9) That the parties shall simultaneously file specified documents or information enclosed in sealed envelopes to be opened as the ALJ directs.

§ 1174.25 Filing and serving documents with the ALJ.

(a) Documents filed with the ALJ must include an original and two copies. Every document filed in the proceeding must contain a title (*e.g.,* motion to quash subpoena), a caption setting forth the title of the action, and the case number assigned by the ALJ. Every document must be signed by the person on whose behalf the paper was filed, or by his or her representative.

(b) Documents are considered filed when they are mailed. The mailing date may be established by a certificate from the party or its representative, or by proof that the document was sent by certified or registered mail.

(c) A party filing a document with the ALJ must, at the time of filing, serve a copy of such document on every other party. When a party is represented by a representative, the party's representative must be served in lieu of the party.

(d) A certificate from the individual serving the document constitutes proof of service. The certificate must set forth the manner in which the document was served.

(e) Service upon any party of any document other than the complaint must be made by delivering a copy or by placing a copy in the United States mail, postage prepaid and addressed to the party's last known address.

(f) If a party consents in writing, documents may be sent electronically. In this instance, service is complete upon transmission unless the serving party receives electronic notification that transmission of the communication was not completed.

§ 1174.26 Computation of time.

(a) In computing any period of time under this part or in an order issued under it, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday that is observed by the Federal government, in which event it includes the next business day.

(b) When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays that are observed by the Federal government are excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional five days will be added to the time permitted for any response.

§ 1174.27 The hearing and the burden of proof.

(a) The ALJ conducts a hearing in order to determine whether a defendant is liable for a civil penalty, assessment, or both and, if so, the appropriate amount of the penalty and/or assessment.

(b) The hearing will be recorded and transcribed. The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding, constitute the record for the ALJ's and the authority head's decisions.

(c) The hearing will be open to the public unless otherwise ordered by the ALJ for good cause shown.

(d) The authority must prove a defendant's liability and any aggravating factors by a preponderance of the evidence.

(e) A defendant must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

§ 1174.28 Presentation of evidence.

(a) The ALJ shall determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ shall not be bound by the Federal Rules of Evidence, but the ALJ may apply the Federal Rules of Evidence where he or she deems appropriate.

(c) The ALJ shall exclude irrelevant and immaterial evidence.

(d) The ALJ may exclude evidence, although relevant, if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) The ALJ shall exclude evidence, although relevant, if it is privileged under Federal law.

(f) Evidence concerning compromise or settlement offers shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) The ALJ shall permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence taken for the record must be open to examination by all parties unless the ALJ orders otherwise.

§ 1174.29 Witness testimony.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the ALJ's discretion, the ALJ may admit testimony in the form of a written statement or deposition. The party offering such a statement must provide it to all other parties along with the last known address of the witness, in a manner which allows sufficient time for other parties to subpoena the witness for cross-examination at the hearing. The parties shall exchange deposition transcripts and prior written statements of witnesses proposed to testify at the hearing as provided in § 1174.22.

(c) The ALJ shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence.

(d) The ALJ shall permit the parties to conduct such cross-examination as may

be required for a full and true disclosure of the facts.

(e) Upon any party's motion, the ALJ shall order witnesses excluded from the hearing room so that they cannot hear the testimony of other witnesses. This rule does not authorize exclusion of—

(1) A party who is an individual;

(2) In the case of a party that is not an individual, the party's officer or employee appearing for the entity pro se or designated by the party's representative; or

(3) An individual whose presence a party shows to be essential to the presentation of its case, including an individual employed by the Government or engaged in assisting the Government's representative.

§ 1174.30 *Ex parte* communications.

A party may not communicate with the ALJ *ex parte* unless the other party consents to such a communication taking place. This does not prohibit a party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 1174.31 Sanctions for misconduct.

(a) The ALJ may sanction a person, including any party or representative, for failing to comply with an order, or for engaging in other misconduct that interferes with the speedy, orderly, and fair conduct of a hearing.

(b) Any such sanction shall reasonably relate to the severity and nature of the misconduct.

(c) When a party fails to comply with an order, including an order for taking a deposition, producing evidence within the party's control, or responding to a request for admission, the ALJ may:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, deem each matter for which an admission is requested to be admitted;

(3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon testimony relating to, the information sought; and

(4) Strike any part of the pleadings or other submissions filed by the party failing to comply with such a request.

(d) The ALJ may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

(e) If a party fails to prosecute or defend an action under this part that is commenced by service of a hearing notice, the ALJ may dismiss the action or may issue an initial decision imposing penalties and assessments.

§ 1174.32 Post-hearing briefs.

Any party may file a post-hearing brief. Such briefs are not required, however, unless ordered by the ALJ. The ALJ must fix the time for filing such briefs, not to exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

Subpart E—Decisions and Appeals

§ 1174.33 Initial decision.

(a) The ALJ will issue an initial decision based only on the record. It will contain findings of fact, conclusions of law, and the amount of any penalties and assessments.

(b) The ALJ will serve the initial decision on all parties within ninety days after the hearing's close or, if the ALJ permitted the filing of post-hearing briefs, within ninety days after the final post-hearing brief was filed.

(c) The findings of fact must include a finding on each of the following issues:

(1) Whether any one or more of the claims or statements identified in the complaint violate this part; and

(2) If the defendant is liable for penalties or assessments, the appropriate amount of any such penalties or assessments, considering any mitigating or aggravating factors.

(d) If the defendant is liable for a civil penalty or assessment, the initial decision shall describe the defendant's right to file a motion for reconsideration with the ALJ or a notice of appeal with the authority head.

§ 1174.34 Determining the amount of penalties and assessments.

In determining an appropriate amount of civil penalties and assessments, the ALJ and the authority head, upon appeal, should evaluate any circumstances that mitigate or aggravate the violation and should articulate in their opinions the reasons that support the penalties and assessments they impose.

§ 1174.35 Reconsideration of the initial decision.

(a) Any party may file a motion with the ALJ for reconsideration of the initial decision within twenty days of receipt of the initial decision. If the initial decision was served by mail, there is a rebuttable presumption that the party received the initial decision five days from the date of mailing.

(b) A motion for reconsideration must be accompanied by a supporting brief and must describe specifically each allegedly erroneous decision.

(c) A party only may file a response to a motion for reconsideration upon the ALJ's request.

(d) The ALJ will dispose of a motion for reconsideration by denying it or by issuing a revised initial decision.

(e) If the ALJ issues a revised initial decision upon a party's motion, no party may file a further motion for reconsideration.

§ 1174.36 Finalizing the initial decision.

(a) Thirty days after issuance, the ALJ's initial decision shall become the authority's final decision and shall bind all parties, unless any party timely files a motion for reconsideration or any defendant adjudged to have submitted a false, fictitious, or fraudulent claim or statement timely appeals to the authority head, as set forth in § 1174.37.

(b) If the ALJ disposes of a motion for reconsideration by denying it or by issuing a revised initial decision, the ALJ's order on the motion for reconsideration shall become the authority's final decision thirty days after the ALJ issues the order, unless a defendant that is adjudged to have submitted a false, fictitious, or fraudulent claim or statement timely appeals to the authority head, as set forth in § 1174.37.

§ 1174.37 Procedures for appealing the ALJ's decision.

(a) Any defendant who submits a timely answer and is found liable in an initial decision for a civil penalty or assessment may appeal the decision.

(b) The defendant may file a notice of appeal with the authority head within thirty days following issuance of the initial decision, serving a copy of the notice of appeal on all parties and the ALJ. The authority head may extend this deadline for up to an additional thirty days if the defendant files an extension request within the initial thirty day period and shows good cause.

(c) The authority head shall not consider a defendant's appeal until all timely motions for reconsideration have been resolved.

(d) If the ALJ denies a timely motion for reconsideration, the defendant may file a notice of appeal within thirty days following such denial or issuance of a revised initial decision, whichever applies.

(e) The defendant must support its notice of appeal with a written brief specifying why the authority head should reverse or modify the initial decision.

(f) The authority's representative may file a brief in opposition to the notice of

appeal within thirty days of receiving the defendant's appeal and supporting brief.

(g) If a defendant timely files a notice of appeal, and the time for filing reconsideration motions has expired, the ALJ will forward the record of the proceeding to the authority head.

(h) An initial decision is automatically stayed pending disposition of a motion for reconsideration or of an appeal to the authority head.

(i) No administrative stay is available following the authority head's final decision.

§ 1174.38 Appeal to the authority head.

(a) A defendant has no right to appear personally, or through a representative, before the authority head.

(b) There is no right to appeal any interlocutory ruling.

(c) The authority head will not consider any objection or evidence that was not raised before the ALJ unless the defendant demonstrates that extraordinary circumstances excuse the failure to object. If the defendant demonstrates to the authority head's satisfaction that extraordinary circumstances prevented the presentation of evidence at the hearing, and that the additional evidence is material, the authority head may remand the matter to the ALJ for consideration of the additional evidence.

(d) The authority head may affirm, reduce, reverse, compromise, remand, or settle any penalty or assessment that the ALJ imposed in the initial decision or reconsideration decision.

(e) The authority head will promptly serve each party to the appeal and the ALJ with a copy of the decision. This decision must contain a statement describing the right of any person, against whom a penalty or assessment has been made, to seek judicial review.

§ 1174.39 Judicial review.

31 U.S.C. 3805 authorizes the appropriate United States District Court to review any final decision imposing penalties or assessments, and specifies the procedures for such review. To obtain judicial review, a defendant must file a petition with the appropriate court in a timely manner.

§ 1174.40 Collection of civil penalties and assessments.

31 U.S.C. 3806 and 3808(b) authorize actions for collecting civil penalties and assessments imposed under this part and specify the procedures for such actions.

§ 1174.41 Rights to administrative offset.

The authority may make an administrative offset under 31 U.S.C. 3716 to collect the amount of any penalty or assessment which has become final, for which a judgment has been entered, or which the parties agree upon in a compromise or settlement. However, the authority may not make an administrative offset under this subsection against a Federal tax refund that the United States owes to the defendant then or at a later time.

§ 1174.42 Deposit in Treasury of the United States.

The authority shall deposit all amounts collected pursuant to this part as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 1174.43 Voluntary settlement of the administrative complaint.

(a) Parties may make offers of compromise or settlement at any time. Any compromise or settlement must be in writing.

(b) The reviewing official has the exclusive authority to compromise or settle the case from the date on which the reviewing official is permitted to issue a complaint until the ALJ issues an initial decision.

(c) The authority head has exclusive authority to compromise or settle the case from the date of the ALJ's initial decision until initiation of any judicial review or any action to collect the penalties and assessments.

(d) The Attorney General has exclusive authority to compromise or settle the case while any judicial review or any action to recover penalties and assessments is pending.

(e) The investigating official may recommend settlement terms to the reviewing official, the authority head, or the Attorney General, as appropriate.

§ 1174.44 Limitations regarding criminal misconduct.

(a) Any investigating official may:

(1) Refer allegations of criminal misconduct or a violation of the False Claims Act directly to the Department of Justice for prosecution and/or civil action, as appropriate;

(2) Defer or postpone a report or referral to the reviewing official to avoid interference with a criminal investigation or prosecution; or

(3) Issue subpoenas under any other statutory authority.

(b) Nothing in this part limits the requirement that the authority's employees must report suspected violations of criminal law to the NEH Office of the Inspector General or to the Attorney General.

Dated: August 2, 2021.

Elizabeth Voyatzis,

Deputy General Counsel, National Endowment for the Humanities.

[FR Doc. 2021–16763 Filed 8–12–21; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[GN Docket No. 13–111; FCC 21–82; FR ID 39494]

Promoting Technological Solutions To Combat Contraband Wireless Device Use in Correctional Facilities

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) takes further steps to facilitate the deployment and viability of technological solutions used to combat contraband wireless devices in correctional facilities. The *Second Report and Order* adopts a framework requiring the disabling of contraband wireless devices detected in correctional facilities upon satisfaction of certain criteria, and we address issues involving oversight, wireless provider liability, and treatment of 911 calls. The *Second Report and Order* further adopts rules requiring advance notice of certain wireless provider network changes to promote and maintain contraband interdiction system effectiveness.

DATES: This final rule is effective September 13, 2021, with the exception of the revisions to § 20.23, which are delayed. The Commission will publish a document in the **Federal Register** announcing the effective date for those revisions.

FOR FURTHER INFORMATION CONTACT: Melissa Conway of the Wireless Telecommunications Bureau, Mobility Division, at (202) 418–2887 or *Melissa.Conway@fcc.gov.* For information regarding the Paperwork Reduction Act of 1995 (PRA) information collection requirements contained in this document, contact Cathy Williams, Office of Managing Director, at (202) 418–2918 or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Second Report and Order* in GN Docket No. 13–111, FCC 21–82 adopted July 12, 2021 and released July 13, 2020. The full text of the *Second Report and Order,* including all Appendices, is available

for inspection and copying during normal business hours in the FCC Reference Center, 45 L Street NE, Washington, DC 20554, or available for viewing via the Commission's ECFS website by entering the docket number, GN Docket No. 13–111. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *FCC504@fcc.gov* or calling the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

The Commission will send a copy of this *Second Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) concerning the possible impact of the rule changes contained in this *Second Report and Order* on small entities. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Further Notice of Proposed Rulemaking* (*FNPRM*) released in March 2017 in this proceeding (82 FR 22780, May 18, 2017). The Commission sought written public comment on the proposals in the *FNPRM,* including comments on the IRFA. No comments were filed addressing the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

Paperwork Reduction Act

The requirements in § 20.23(b) through (d) include new or modified collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. They will be submitted to the Office of Management and Budget (OMB) for review under Section 3507(d) of the PRA. OMB, the general public, and other Federal agencies will be invited to comment on the new or modified information collection requirements contained in this proceeding. In addition, the Commission notes that, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the Commission previously sought, but did not receive, specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees. The Commission describes impacts that might affect small businesses, which includes more businesses with fewer than 25 employees, in the Final Regulatory Flexibility Analysis.

Congressional Review Act

The Commission will send a copy of this *Second Report and Order* to Congress and the Government Accountability Office pursuant to the Congressional Review Act. *See* 5 U.S.C. 801(a)(1)(A). In addition, the Commission will send a copy of the *Second Report and Order,* including this FRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). A copy of the *Second Report and Order,* and FRFA (or summaries thereof) will also be published in the **Federal Register**.

Synopsis

1. The *Second Report and Order* adopts new or additional reporting or recordkeeping and compliance obligations for small entities as well as other applicants and licensees. Small entities may have to hire attorneys, engineers, consultants, or other professionals in order to meet the reporting, recordkeeping or compliance obligations in the *Second Report and Order,* however, the Commission cannot quantify the cost of compliance with the requirements. To minimize burdens, we have adopted processes and procedures where possible to allow direct interaction between the Designated Correctional Facility Officials (DCFOs) and the wireless providers and avoided interjecting the Commission and additional regulations into the process. In our approach, we sought to provide small and other entities flexible options such as giving DCFOs and wireless providers the flexibility to structure the format of the qualifying requests in a way that meets the unique needs of the parties rather than adopting a standardized form. We also adopted minimum requirements for information to be included in a qualifying request to disable a contraband device and allowed for self-certification to meet the certification requirements. Below we discuss reporting, recordkeeping, and/or compliance requirements adopted in the *Second Report and Order.*

2. *Designated Correctional Facility Official Requirements.* The *Second Report and Order* requires that a DCFO satisfy certain requirements in order to submit qualifying requests to wireless providers. Specifically, qualifying disabling requests must be submitted by a DCFO, which we define as an official of the state, local, or Federal government with responsibility for oversight of the relevant facility. In government-run correctional facilities, this definition requires the DCFO to be, at a minimum, the official with responsibility for oversight of the relevant facility (*e.g.,* the warden) or higher ranking official; in privately-run correctional facilities, the DCFO must be a government official with responsibility for oversight of the facility's performance through a contract.

3. The *Second Report and Order* also adopts a process for certification of DCFOs that will provide certainty to wireless providers that disabling requests are duly authorized by the relevant Federal, state, or local government entities. The Commission will maintain a publicly available list of DCFOs that are authorized to transmit qualifying disabling requests. Authorized individuals that wish to be recognized on the Commission's DCFO list must send a letter to the Commission's Contraband Ombudsperson, signed by the relevant state attorney general, providing the individual's name, official government position, and a list of correctional facilities over which the individual has oversight and management authority.

4. *Authorization of CISs.* The *Second Report and Order* establishes a two-phase authorization process for Contraband Interdiction System (CIS) applicants seeking to deploy CISs that will provide the requisite information necessary for DCFOs to submit qualifying requests to disable contraband devices at qualifying correctional facilities. In phase one, CIS applicants will submit applications to the Wireless Telecommunications Bureau (the Bureau) describing their legal and technical qualifications of the systems. The Bureau will review the applications and approve—at a system level—those CISs that meet the requirements. In phase two, CIS applicants will perform on-site testing of approved CISs at individual qualifying correctional facilities. After both phases are complete, DCFOs will be authorized to submit qualifying requests to disable contraband devices using approved CISs at each approved correctional facility.

5. *CIS Certification Process.* The *Second Report and Order* adopts a CIS certification process for detection systems to be used in qualifying requests. To obtain CIS certification, a CIS applicant must submit an application to the Bureau for review and

approval. The application must demonstrate, at a minimum that: (1) All radio transmitters used as part of the CIS have appropriate equipment authorization pursuant to Commission rules; (2) the CIS is designed and will be configured to locate devices solely within a correctional facility; (3) the methodology to be used in analyzing data collected by the CIS is sufficiently robust to ensure that the particular wireless device is in fact located within a correctional facility, including specific data analysis benchmarks designed to ensure successful detection, such as rate of detection of contraband versus non-contraband devices, relevant sample size (*e.g.* number of devices observed and length of observation period); (4) the CIS will secure and protect all information or data collected as part of its intended use; and (5) the CIS will not interfere with emergency 911 calls. The application must also include a description of whether the CIS requires a spectrum or network access agreement (*e.g.,* a spectrum leasing arrangement and/or roaming agreement) to be authorized to operate. Finally, the application must include a proposed test plan for subsequent site-based testing of each CIS, which must include detailed descriptions and technical specifications to facilitate Commission review of whether the system satisfies its legal requirements and technically functions as anticipated.

6. *Site-Based Testing and Self-Certification Requirement.* In the second phase of the CIS authorization process, a CIS operator—which could be a CIS solutions provider, or a DCFO or other responsible party that deploys its own CIS at a correctional facility [1]—seeking to use the CIS to submit qualifying requests for disabling contraband devices must test a certified CIS at each location and, thereafter, must file a self-certification to the Bureau confirming that the testing at that specific correctional facility is complete and successful. The CIS operator must also serve notice of the testing on each of the wireless providers holding a spectrum license that includes the county within which the correctional facility is located and provide a reasonable opportunity to participate in the tests. Following the testing, and to be eligible for use in conjunction with qualifying requests for disabling, the CIS operator must submit a self-certification that: (1) Identifies the correctional facility where it seeks to deploy; (2) attests that applicable federal or state criminal statutes prohibit possession or operation of contraband devices within the correctional facility (and includes the applicable federal or state criminal statutory provision); (3) describes the results of on-site tests of the certified CIS conducted at the correctional facility; (4) attests that the on-site testing was performed consistent with the approved test plans for the certified CIS and that the CIS deployment minimizes the risk of disabling a non-contraband device; (5) identifies whether any wireless providers participated in the testing, and provides proof that the wireless providers were given notice regarding the testing and a reasonable opportunity to participate; and (6) includes proof of any spectrum and/or network access agreement (*e.g.,* a spectrum leasing arrangement and/or roaming agreement) required to be authorized to operate and/or for the system to function effectively. The self-certification submitted by a CIS operator must be accompanied by an attestation from the DCFO verifying that all information contained in the self-certification is true and accurate.

7. CIS operators must submit self-certifications in accordance with filing procedures established by the Bureau and those certifications must also be served via electronic means on all wireless providers licensed in the geographic area occupied by the correctional facility. Wireless providers have five business days from the certification filing date to submit objections to the Bureau and to serve any such objections on the DCFO and the CIS operator. Absent objections, the DCFO may submit qualifying requests to wireless providers beginning on the sixth business day after the certification filing. If an objection is submitted, the DCFO may not submit qualifying requests until the Bureau addresses the objection.

8. *Records Maintenance.* To ensure the integrity and proper operation of CIS, we require CIS operators to retain records of all information supporting each request for disabling and the basis for disabling each device, for at least five years following the relevant disabling request. CIS operators of systems that have been tested and approved for use in qualifying requests must also make available all records upon request from the Bureau.

9. *Recertification.* In order to ensure the ongoing accuracy and reliability of a given CIS at a particular facility, at least every three years after the initial self-certification, CIS operators seeking to maintain the ability to submit qualifying requests through a DCFO to disable contraband devices must retest their systems and recertify them for continued CIS accuracy. Recertifications must comply with the same rules and filing instructions that apply to the initial self-certification.

10. *Qualifying Requests.* We required that qualifying requests to disable a contraband device include the following material: (1) A certification that (a) A certified CIS was used to gather the contraband subscriber and device information populated in the qualifying request; (b) the certified CIS was used to identify contraband devices operating in a correctional facility where the CIS has been tested and self-certified for operational readiness and for use in qualifying requests, and the identification of contraband devices occurred within 30 days immediately prior to the date of the qualifying request submission; (c) the DCFO has reviewed the list of contraband devices and attests that it is accurate; and (d) it is a violation of applicable state or federal criminal statutes to possess or operate a contraband device in the correctional facility; (2) the name and address of each requesting correctional facility; and (3) a list of contraband devices with identifiers sufficient to uniquely describe the devices in question at both the subscription and device level.

11. *Disabling Process and Timeframe for Disabling a Contraband Device.* The *Second Report and Order* adopts the following process for disabling contraband devices. Upon receipt of a qualifying request from a DCFO through a verifiable and secure transmission method, a wireless provider must treat the request as valid. The wireless provider may only reject a request if the request fails to meet the Commission-mandated information for a qualifying request or if there are errors with respect to the device identifying information that leave the wireless provider unable to disable the device. Unless a wireless provider finds these grounds to reject the qualifying request, it must, within two business days after receipt of a qualifying request: (1) Disable the device at both the subscriber level and at the device level; and (2) take reasonable and practical steps to prevent an identified device from being accessing another wireless provider's network (*e.g.,* by adding the equipment identifier to the Stolen Phone Database). A wireless provider must inform the DCFO whether or not the request has been granted within two business days of receiving the qualifying request.

12. *Reversals.* A wireless provider may subsequently reverse a device disabling if it determines that the device was identified erroneously as

[1] *See* Appendix A, Final Rules, of the Second Report and Order (adding definition to § 20.3 of the Commission's rules, 47 CFR 20.3).

contraband. If the wireless provider chooses to reverse a disabling, however, it must promptly inform the DCFO of the mistakenly identified device. The *Second Report and Order* also provides wireless providers with the option to trigger the involvement of the DCFO in the reviewing the validity of a device previously identified and disabled as contraband. If the wireless provider seeks to trigger the DCFO's involvement, it must provide the DCFO with: (1) The date of the qualifying request, (2) the identifying information provided for the device, and (3) any evidence supporting the wireless provider's belief that the device was erroneously identified. The *Second Report and Order* states that, upon receipt of such a request, the DCFO should review the qualifying request to determine whether the device in question was erroneously identified and either: (1) Confirm the validity of the identifying information contained in the qualifying request, or (2) acknowledge the error and direct the carrier to restore service to the device. In the event the DCFO directs the wireless provider to reverse the disabling, the wireless provider must, within two business days, restore service to the device and reverse any actions taken to prevent the device from accessing other wireless provider networks (*e.g.,* by removing the phone from the Stolen Phone Database). In the event the DCFO does not respond to a request from a wireless provider for review of a qualifying request within two business days, the wireless provider may proceed with reversing the disabling action. The *Second Report and Order* requires the DCFO to provide notice to the Contraband Ombudsperson of the number of erroneously disabled devices on a quarterly basis at the end of any quarter during which a device disabling was reversed, and directs the Wireless Telecommunications Bureau to issue a public notice providing additional guidance regarding the appropriate method for providing such notice.

13. *Transmission of the Qualifying Request.* DCFOs must transmit a qualifying request to a wireless provider using a verifiable and secure transmission method, and a wireless provider must adopt a method, or utilize an existing method, for receiving secured and verified qualifying requests. The *Second Report and Order* directs the Contraband Ombudsperson to work with wireless providers to develop suitable methods for securely transmitting a qualifying request.

14. *Notification to CIS Operators of Wireless Provider Technical Changes.* Commercial Mobile Radio Service (CMRS) licensees leasing spectrum to managed access systems (MAS) must provide 90 days advance notice to MAS operators of the following network changes occurring within 15 miles of the correctional facility, while permitting modified notice arrangements through mutual agreement: (1) Adding a new frequency band to service offerings; (2) deploying a new air interface technology or changing an existing air interface technology; and/or (3) adding, relocating, or removing a site. This limited notification requirement is necessary to deploy MAS effectively. The *Second Report and Order* adopts an exception to the 90-day advance notice requirement for network technical changes within 15 miles of the facility that are required due to emergency/disaster preparedness, but it requires CMRS licensees to provide notice of these technical changes immediately after the exigency. The *Second Report and Order* also requires CMRS licensee lessors and MAS operator lessees to negotiate in good faith to reach an agreement for notification for other, more localized types of network adjustments not covered bv the major network change notice requirement. The *Second Report and Order* further requires CMRS licensees and MAS operators to negotiate in good faith regarding the parties' treatment of confidential information contained in notifications required by rule and/or negotiated between the parties.

List of Subjects in 47 CFR Part 20

Administrative practice and procedure, Common carriers, Communications, Communications common carriers, Communications equipment, Environmental impact statements, Radio, Reporting and recordkeeping requirements, Satellites, Security measures, Telecommunications, Telephone.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 20 as follows:

PART 20—COMMERCIAL MOBILE SERVICES

■ 1. The authority citation for part 20 continues to read as follows:

Authority: 47 U.S.C. 151, 152(a), 154(i), 155, 157, 160, 201, 214, 222, 251(e), 301, 302, 303, 303(b), 303(r), 307, 307(a), 309, 309(j)(3), 316, 316(a), 332, 610, 615, 615a, 615b, and 615c, unless otherwise noted.

■ 2. Amend § 20.3 by adding the definitions of ''CIS Operator,'' ''Contraband Interdiction System,'' ''Designated Correctional Facility Official,'' ''Managed Access System'' in alphabetical order to read as follows:

§ 20.3 Definitions.

* * * * *

CIS Operator. An operator of a CIS at a correctional facility, whether a CIS solutions provider, or a DCFO or responsible party that deploys its own CIS at a correctional facility.

* * * * *

Contraband Interdiction System. A Contraband Interdiction System (CIS) is any system comprised of one or more stations that is used only at a permanent correctional facility that is authorized to operate such systems pursuant to this part and that is designed exclusively to prevent transmissions to or from contraband wireless devices within the boundaries of the facility and/or to obtain identifying information from such contraband wireless devices.

Designated Correctional Facility Official. A Designated Correctional Facility Official (DCFO) is an official of the state, local, or Federal government responsible for administration and oversight of the relevant correctional facility where a contraband wireless device is located.

(1) In government-run correctional facilities, this definition requires the DCFO to be, at a minimum, the official with responsibility for oversight of the relevant facility (*e.g.,* the warden) or higher ranking official.

(2) In privately-run correctional facilities, this definition requires the DCFO to be a government official with responsibility for oversight of the facility's performance through contract.

* * * * *

Managed Access System. A Managed Access System (MAS) is a Contraband Interdiction System whose operations require:

(1) One or more lease agreements with CMRS operators; and

(2) Real-time awareness of wireless provider spectrum use in the vicinity of the correctional facility where it is deployed.

* * * * *

■ 3. Delayed indefinitely, amend § 20.23 by adding paragraphs (b) through (d) to read as follows:

§ 20.23 Contraband wireless devices in correctional facilities.

* * * * *

(b) *Contraband Interdiction System (CIS) authorization process.* The

provisions in this section apply to any person seeking certification of a CIS authorized for use in the submission of qualifying disabling requests, whether operating a system that requires a license and is regulated as CMRS or private mobile radio service (PMRS), or operating a passive system that does not require a license. The Wireless Telecommunications Bureau (Bureau) will establish, via public notice, the form and procedure for: CIS operators to file CIS certification applications, self-certifications, and periodic re-certification; CIS operators to serve on wireless providers notice of testing and copies of self-certification; and wireless providers to file objections to self-certifications, including required service on CIS operators and DCFOs.

(1) *Application requirements.* To obtain CIS certification, an applicant must submit an application to the Bureau for review and approval that:

(i) Demonstrates that all radio transmitters used as part of the CIS have appropriate equipment authorizations pursuant to Commission rules in part 2 of this chapter;

(ii) Demonstrates that the CIS is designed and will be configured to locate devices solely within a correctional facility;

(iii) Describes the methodology to be used in analyzing data collected by the CIS and demonstrates that such methodology is adequately robust to ensure that the particular wireless device is in fact located within a correctional facility and includes specific data analysis benchmarks designed to ensure successful detection, such as rate of detection of contraband versus non-contraband devices and relevant sample size (*e.g.* number of devices observed and length of observation period);

(iv) Demonstrates that the CIS will secure and protect all information or data collected as part of its intended use;

(v) Demonstrates that the CIS will not interfere with emergency 911 calls;

(vi) Describes whether the CIS requires a spectrum or network access agreement (*e.g.,* a spectrum leasing arrangement or roaming agreement) to be authorized to operate; and

(vii) Includes a proposed test plan for subsequent site-based testing of each CIS, that must include detailed descriptions and technical specifications to facilitate Commission review of whether the system satisfies its legal requirements and technically functions as anticipated.

(2) *Marketing and sales.* CIS that are certified for use in qualifying requests for disabling of contraband devices may be marketed or sold only to correctional facilities or entities that will provide contraband interdiction services to such facilities.

(3) *Site-based testing and self-certification requirements*—(i) *Site-based testing.* A CIS operator seeking to use the CIS to submit qualifying requests for disabling must test a certified CIS at each location where it intends to operate. Thereafter, the CIS operator must file with the Bureau a self-certification that complies with paragraph (b)(3)(ii) of this section, confirming that the testing at that specific correctional facility is complete and successful. The CIS operator must serve notice of the testing on all relevant wireless providers prior to testing and provide such wireless providers a reasonable opportunity to participate in the tests. Relevant wireless providers include any wireless provider holding a spectrum license that:

(A) Authorizes operation on the frequencies on which the CIS seeks to detect contraband use; and

(B) Authorizes service in the geographic area (*e.g.,* census tract, county, Partial Economic Area (PEA), Economic Area (EA), Cellular Market Area (CMA), Regional Economic Area Grouping (REAG)) within which the correctional facility is located.

(ii) *Self-certification.* Following the testing, and to be eligible for use in conjunction with qualifying requests for disabling, a CIS operator must file a self-certification with the Bureau that:

(A) Identifies the correctional facility where it seeks to deploy;

(B) Attests that applicable Federal or state criminal statutes prohibit the possession or operation of contraband devices within the correctional facility (and includes the applicable Federal or state criminal statutory provision);

(C) Describes the results of on-site tests of the certified CIS conducted at the correctional facility;

(D) Attests that the on-site testing was performed consistent with the approved test plans for the certified CIS and that the CIS deployment minimizes the risk of disabling a non-contraband device;

(E) Identifies whether any relevant wireless providers participated in the testing, and provides proof that the relevant wireless providers were given notice regarding the testing and a reasonable opportunity to participate;

(F) Includes proof of any spectrum and/or network access agreement (*e.g.,* a spectrum leasing arrangement and/or roaming agreement) required to be authorized to operate and/or for the system to function effectively;

(G) Includes proof that the self-certification was served via electronic means on all relevant wireless providers; and

(H) Includes an attestation from the DCFO verifying that all information contained in the self-certification is true and accurate.

(I) The self-certification must be filed in accordance with part 1, subpart F, of this chapter.

(4) *Submitting objections.* Wireless providers may submit objections to the Bureau within five business days from the certification filing date. Any such objections must be served on the DCFO and the CIS operator.

(5) *Recertification.* At least every three years after the initial self-certification, CIS operators seeking to maintain the ability to submit qualifying requests through a DCFO for contraband device disabling must retest their systems and recertify them for continued CIS accuracy. Recertifications must comply with the same rules and filing instructions that apply to the initial self-certification.

(6) *Suspension of CIS eligibility.* The Bureau may suspend CIS certification generally or at a particular facility if subsequent credible information calls into question a system's reliability.

(7) *Records maintenance.* To ensure the integrity and proper operation of CISs, a CIS operator must retain records of all information supporting each request for disabling and the basis for disabling each device, including copies of all documents submitted in the qualifying request, for at least five years following the date of submission of the relevant disabling request. CIS operators of systems that have been tested and approved for use in qualifying requests must make available all records upon request from the Bureau.

(c) *Disabling contraband wireless devices.* A DCFO may request that a CMRS licensee disable a contraband wireless device that has been detected in a correctional facility by a CIS that has been certified in accordance with paragraph (b) of this section. Absent objections from a wireless provider, as described under paragraph (b)(4) of this section, the DCFO may submit a qualifying request to a wireless provider beginning on the sixth business day after the later of the self-certification filing or actual service, as described under paragraph (b)(3)(ii) of this section.

(1) *DCFO list.* The Commission will maintain a publicly available list of DCFOs that are authorized to transmit qualifying disabling requests. Authorized DCFOs that seek to be recognized on the Commission's DCFO list must send a letter to the Commission's Contraband Ombudsperson, signed by the relevant

state attorney general or the relevant Bureau of Prisons Regional Director and providing:

(i) The individual's name;

(ii) The individual's official government position; and

(iii) A list of correctional facilities over which the individual has oversight and management authority.

(2) *Qualifying request.* A qualifying request must be made in writing, contain the certifications in paragraph (c)(2)(i) of this section and the device and correctional facility identifying information in paragraph (c)(2)(ii) of this section, and be signed by the appropriate DCFO. The DCFO must transmit a qualifying request to a CMRS licensee using a secure communication means that will provide certainty regarding the identity of both the sending and receiving parties. A CMRS licensee must adopt a method, or use an existing method, for receiving secured and verified qualifying requests.

(i) *Certifications.* A qualifying request must include the following certifications by the DCFO:

(A) A CIS that has been certified in accordance with paragraph (b) of this section was used to gather the contraband subscriber and device information populated in the qualifying request;

(B) The certified CIS was used to identify contraband wireless devices operating in a correctional facility where the CIS has been tested and self-certified for operational readiness and for use in qualifying requests, and the identification of contraband wireless devices occurred within 30 days immediately prior to the date of the qualifying request submission;

(C) The DCFO has reviewed the list of contraband wireless devices and attests that it is accurate; and

(D) It is a violation of applicable state or Federal criminal statutes to possess or operate a contraband device in the correctional facility.

(ii) *Device and correctional facility identifying information.* The qualifying request must identify the contraband wireless device to be disabled and the correctional facility by providing the following information:

(A) Identifiers sufficient to:

(*1*) Identify the applicable wireless service provider;

(*2*) Uniquely describe each of the contraband wireless devices in question at the subscription level; and

(*3*) Uniquely describe each of the contraband wireless devices in question at the device-level;

(B) Name of the correctional facility at which the contraband wireless device(s) were identified; and

(C) Street address of the correctional facility at which the contraband wireless device(s) were identified.

(3) *Licensee actions upon receipt of a qualifying request.* Upon receiving a request from a DCFO to disable a contraband wireless device, a licensee providing CMRS service must verify that the request contains the required information for a qualifying request, as defined in paragraph (c)(2) of this section.

(i) *Disabling upon receipt of a qualifying request and timing.* If the qualifying request contains the required information, and does not contain an error in the device identifying information preventing the licensee from being able to disable the device, a licensee must, within two business days of receipt of the qualifying request, disable the contraband wireless device from using the wireless provider's network at both the device and subscriber level and take reasonable and practical steps to prevent the contraband wireless device from being used on another wireless provider's network.

(ii) *Rejection of a qualifying request and timing.* A licensee may reject a qualifying request within two business days of receipt of a qualifying request if it does not include the information required for a qualifying request or, with respect to a relevant device, the request contains an error in the device-identifying information preventing the licensee from being able to disable the device.

(iii) *Customer outreach.* A licensee may immediately disable a contraband wireless device without any customer outreach, or a licensee may contact the customer of record through any available means to notify them that the device will be disabled, but any such notice does not modify the licensee's obligation to comply with paragraphs (c)(3)(i) and (ii) of this section.

(iv) *Notification to the Designated Correctional Facility Official.* Within two business days of receiving a qualifying request from a DCFO, a licensee must inform the DCFO whether the request has been granted or rejected.

(4) *Reversals.* A licensee may reverse a disabled wireless device if it determines that the wireless device was identified erroneously as contraband. The licensee must promptly inform the DCFO of the erroneously identified wireless device.

(i) *DCFO involvement.* Prior to reversing a disabling action, a wireless provider that determines that a device may have been erroneously identified as contraband may request that the DCFO review and confirm the information provided in a qualifying request pursuant to which the device was previously disabled. To trigger DCFO involvement, the wireless provider must provide the DCFO with:

(A) The date of the qualifying request;

(B) The identifying information provided for the device; and

(C) Any evidence supporting the wireless provider's belief that the device was erroneously identified.

(ii) *DCFO response.* Upon receipt of a request from a wireless provider, the DCFO should review the qualifying request and determine whether the device in question was erroneously identified and either confirm the validity of the identifying information contained in the qualifying request or acknowledge the error and direct the carrier to restore service to the device.

(iii) *Restoration of service.* In the event the DCFO directs the wireless provider to reverse the disabling, the wireless provider must, within two business days, restore service to the device and reverse any actions taken to prevent the device from accessing other wireless provider networks.

(iv) *Wireless provider action in absence of timely DCFO response.* In the event the DCFO does not respond to a request from a wireless provider for review of a qualifying request within two business days, the wireless provider may proceed with reversing the disabling action.

(v) *Notice of reversals.* The DCFO must provide notice to the Contraband Ombudsperson of the number of erroneously disabled devices on a quarterly basis at the end of any quarter during which a device disabling was reversed.

(d) *Notification to Managed Access System (MAS) operators of wireless provider technical changes*—(1) *Notification requirements.* CMRS licensees leasing spectrum to MAS operators must provide 90 days' advance notice to MAS operators of the following network changes occurring within 15 miles of the correctional facility, unless parties modify notification arrangements through mutual agreement:

(i) Adding a new frequency band to service offerings;

(ii) Deploying a new air interface technology or changing an existing air interface technology; and/or

(iii) Adding, relocating, or removing a site.

(2) *Good faith negotiations.* CMRS licensee lessors and MAS operator lessees must negotiate in good faith to reach an agreement for notification for other types of network adjustments not covered by the notice requirement set

forth in paragraph (d)(1) of this section and for the parties' treatment of confidential information contained in notifications required pursuant to this section and/or negotiated between the parties.

(3) *Emergency network changes exception.* CMRS licensees leasing spectrum to managed access systems (MAS) operators are not required to provide 90 days' advance notice to MAS operators of network technical changes occurring within 15 miles of the correctional facility that are required due to emergency and disaster preparedness. CMRS licensees must provide notice of these technical changes immediately after the exigency.

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Proposed Rules

Federal Register
Vol. 86, No. 154
Friday, August 13, 2021

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Part 1630

Privacy Act: Proposed Exemptions

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Notice of proposed rulemaking.

SUMMARY: In accordance with the Privacy Act of 1974, the Federal Retirement Thrift Investment Board (FRTIB) proposes to exempt five systems of records from certain requirements of the Act. FRTIB has previously published System of Records Notices (SORNs) for these systems.

DATES: Comments on this notice of proposed rulemaking must be received by September 13, 2021.

ADDRESSES: You may submit written comments to FRTIB through the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the website instructions for submitting comments.
- *Fax:* 202–942–1676.
- *Mail or Hand Delivery:* Office of General Counsel, Federal Retirement Thrift Investment Board, 77 K Street NE, Suite 1000, Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Dharmesh Vashee, General Counsel and Senior Agency Official for Privacy, Federal Retirement Thrift Investment Board, Office of General Counsel, 77 K Street NE, Suite 1000, Washington, DC 20002, (202) 942–1600.

SUPPLEMENTARY INFORMATION: FRTIB proposes to revise its Privacy Act regulations at 5 CFR part 1630 to exempt five of its systems of records, FRTIB–2, FRTIB–13, FRTIB–14, FRTIB–15, and FRTIB–23, from certain requirements of the Privacy Act, 5 U.S.C. 552a. The FRTIB is promulgating exemptions to the Privacy Act for these five systems of records in accordance with subsection (k)(2) and subsection (k)(5).

Subsection (k)(2) of the Privacy Act authorizes the head of an agency to exempt a system of records from the applicable subsections if investigatory records are compiled for law enforcement purposes; provided, however if an individual is denied any right, privilege, or benefit that he or she would otherwise be entitled by Federal law, or for which he or she would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence. Subsection (k)(5) of the Privacy Act authorizes the head of an agency to exempt a system of records from the applicable subsections if investigatory records are compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence.

Under the Privacy Act, individuals have a right of access to information pertaining to them which is contained in a system of records. At the same time, the Privacy Act permits certain types of systems to be exempt from some Privacy Act requirements. If an agency claims an exemption, however, it must issue a Notice of Proposed Rulemaking to make clear to the public the reasons why a particular exemption is being claimed.

As indicated in the Agency's accompanying Privacy Act system of records notices proposing and modifying these systems of records, these five systems of records contain information collected by the Agency in the course of carrying out its duties under 5 U.S.C. 8401.

The FRTIB is promulgating exemptions under subsections (k)(2) and (k)(5) for FRTIB–2, *Personnel Security Investigation Files*. FRTIB–2 contains information compiled by the Agency in order to document and support decisions regarding clearance for access to sensitive FRTIB information and the suitability, eligibility, and fitness for service of applicants for federal employment and contract positions. FRTIB has previously published a SORN for this system in the **Federal Register**, 85 FR 43654, 43655 (July 21, 2020). FRTIB's personnel investigations records fall under the exemption stated within subsection (k)(2) of the Privacy Act because these records may be used to help streamline and make more efficient the investigations and adjudications process, and may be used to document security violations and actions taken in response to such violations. FRTIB's personnel investigations records also fall under the exemption stated within subsection (k)(5) of the Privacy Act because these records are compiled for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information. FRTIB proposes to exempt eligible records contained within FRTIB–2 from the requirements of subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), (I); and (f), which require agencies to provide an accounting of disclosures; provide notification, access, and amendment rights, rules, and procedures; maintain only relevant and necessary information; and identify categories of record sources. Exempting records from this system is necessary and appropriate to maintain the integrity of personnel investigations and to ensure that FRTIB's efforts to obtain accurate and objective information will be successful. To the extent that FRTIB uses investigatory material within this system of records as a basis for denying an individual any right, privilege, or benefit to which an individual would be entitled in the absence of that record, FRTIB will grant that individual access to the material except to the extent that access would reveal the identity of a source promised confidentiality.

The FRTIB is promulgating exemptions under subsection (k)(2) for FRTIB–13, *Fraud and Forgery Records*. FRTIB–13 contains information compiled by the Agency in the course of carrying out its fiduciary duties to detect and prevent fraudulent activity against participant accounts. FRTIB has previously published a SORN for this system in the **Federal Register**, 84 FR 12249 (April 1, 2019), and a notice of proposed rulemaking for the exemptions, 84 FR 12954 (April 3, 2019). This notice of proposed

rulemaking supersedes the previous notice. FRTIB's fraud and forgery records fall under the exemption stated within subsection (k)(2) of the Privacy Act because these records are compiled for law enforcement purposes. FRTIB proposes to exempt eligible records contained within FRTIB–13 from the requirements of subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), (I); and (f), which require agencies to provide an accounting of disclosures; provide notification, access, and amendment rights, rules, and procedures; maintain only relevant and necessary information; and identify categories of record sources. Exempting records from this system is necessary and appropriate to maintain the integrity of FRTIB's investigations into allegations of fraud or forgery and to ensure that FRTIB's efforts to obtain accurate and objective information will be successful. To the extent that FRTIB uses investigatory material within this system of records as a basis for denying an individual any right, privilege, or benefit to which an individual would be entitled in the absence of that record, FRTIB will grant that individual access to the material except to the extent that access would reveal the identity of a source promised confidentiality.

The FRTIB is promulgating exemptions under subsection (k)(2) for FRTIB–14, *Legal Case Files*. FRTIB–14 contains information compiled by the Agency in the course of its duties to provide legal advice to FRTIB personnel and respond appropriately to claims and litigation. FRTIB has previously published a SORN for this system in the **Federal Register**, 85 FR 43654, 43666 (July 21, 2020). FRTIB's legal case files fall under the exemption stated within subsection (k)(2) of the Privacy Act because these records may be compiled for law enforcement purposes. FRTIB proposes to exempt eligible records contained within FRTIB–14 from the requirements of subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), (I); and (f), which require agencies to provide an accounting of disclosures; provide notification, access, and amendment rights, rules, and procedures; maintain only relevant and necessary information; and identify categories of record sources. Exempting records from this system is necessary and appropriate to maintain the integrity of FRTIB's legal case files and to ensure that FRTIB's efforts to obtain accurate and objective information will be successful. To the extent that FRTIB uses investigatory material within this system of records as a basis for denying an individual any right, privilege, or benefit to which an individual would be entitled in the absence of that record, FRTIB will grant that individual access to the material except to the extent that access would reveal the identity of a source promised confidentiality.

The FRTIB is promulgating exemptions under subsection (k)(2) for FRTIB–15, *Internal Investigations of Harassment and Hostile Work Environment Allegations*. FRTIB–15 contains information compiled by the Agency in the course of upholding FRTIB's policy to provide for a work environment free from all forms of harassment. FRTIB has previously published a SORN for this system in the **Federal Register**, 85 FR 43654, 43669 (July 21, 2020). FRTIB's internal investigations and hostile work environment allegations files fall under the exemption stated within subsection (k)(2) of the Privacy Act because these records may be compiled for law enforcement purposes. FRTIB proposes to exempt eligible records contained within FRTIB–15 from the requirements of subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), (I); and (f), which require agencies to provide an accounting of disclosures; provide notification, access, and amendment rights, rules, and procedures; maintain only relevant and necessary information; and identify categories of record sources. Exempting records from this system is necessary and appropriate to maintain the integrity of FRTIB's investigations into allegations of insider threats and to ensure that FRTIB's efforts to obtain accurate and objective information will be successful. To the extent that FRTIB uses investigatory material within this system of records as a basis for denying an individual any right, privilege, or benefit to which an individual would be entitled in the absence of that record, FRTIB will grant that individual access to the material except to the extent that access would reveal the identity of a source promised confidentiality.

The FRTIB is promulgating exemptions under subsection (k)(2) for FRTIB–23, *Insider Threat Program Records*. FRTIB–23 contains information compiled by the Agency in the course of performing insider threat program functions. The FRTIB has published a SORN for this system in the **Federal Register**, 86 FR 40564 (July 28, 2021). Insider threat program records fall under the exemption stated within subsection (k)(2) of the Privacy Act because these records are compiled for law enforcement purposes. FRTIB proposes to exempt eligible records contained within FRTIB–23 from the requirements of subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), (I); and (f), which require agencies to provide an accounting of disclosures; provide notification, access, and amendment rights, rules, and procedures; maintain only relevant and necessary information; and identify categories of record sources. Exempting records from this system is necessary and appropriate to maintain the integrity of FRTIB's investigations into allegations of insider threats and to ensure that FRTIB's efforts to obtain accurate and objective information will be successful. To the extent that FRTIB uses investigatory material within this system of records as a basis for denying an individual any right, privilege, or benefit to which an individual would be entitled in the absence of that record, FRTIB will grant that individual access to the material except to the extent that access would reveal the identity of a source promised confidentiality.

These exemptions apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552a(k). Where FRTIB determines compliance would not appear to interfere with or adversely affect the purpose of this system to investigate and prevent insider threats, the applicable exemption may be waived by FRTIB in its sole discretion.

Exemptions from the particular subsections are necessary and appropriate, and justified for the following reasons:

• *5 U.S.C. 552a(c)(3) (the requirement to provide accountings of disclosures) and 5 U.S.C. 552a(d)(1)–(4) (requirements addressing notification, access, and amendment rights, collectively referred to herein as access requirements).* Providing individuals with notification, access, and amendment rights with respect to allegations and investigations into personnel investigations, fraud against participant accounts, legal case files, internal investigations of harassment and hostile work environment allegations, or investigations of potential insider threats could reveal the existence of an investigation; investigative interest; investigative techniques; details about an investigation; security-sensitive information, such as information about security measures and security vulnerabilities; information that must remain non-public to protect personal privacy; identities of law enforcement personnel; or other sensitive or Privacy Act-protected information. Revealing such information to individuals could compromise or otherwise impede pending and future law enforcement investigations and efforts to protect sensitive information. Revealing such information could also violate personal

privacy. Additionally, revealing this information could enable individuals to evade detection and apprehension by security and law enforcement personnel; destroy, conceal, or tamper with evidence or fabricate testimony; or harass, intimidate, harm, coerce, or retaliate against witnesses, complainants, investigators, security personnel, law enforcement personnel, or their family members, their employees, or other individuals. With respect to investigatory material compiled for law enforcement purposes, the exemption pursuant to 5 U.S.C. 552a(k)(2) from access requirements in subsection (d) of the Act is statutorily limited. If any individual is denied a right, privilege, or benefit to which the individual would otherwise be entitled by Federal law or for which the individual would otherwise be eligible, access will be granted, except to the extent that the disclosure would reveal the identity of a source who furnished the information to the Government under an express promise of confidentiality.

• *5 U.S.C. 552a(e)(1) (the requirement to maintain only relevant and necessary information authorized by statute or Executive Order).* It will not always be possible to determine at the time information is received or compiled in these systems of records whether the information is or will be relevant and necessary to a law enforcement investigation. For example, a tip or lead that does not initially appear relevant or necessary may prove useful when combined with other information that reveals a pattern or that comes to light later.

• *5 U.S.C. 552a(e)(4)(G) and (H) (the requirements to describe procedures by which subjects may be notified of whether the system of records contains records about them and seek access or amendment of a record).* These requirements concern individual access to records, and the records are exempt under subsections (c) and (d) of the Act, as described above. To the extent that subsection (e)(4)(G) and (H) are interpreted to require the Agency to promulgate more detailed procedures regarding record notification, access, or amendment than have been published in the **Federal Register**, exemption from those provisions is necessary for the same rationale as applies to subsections (c) and (d).

• *5 U.S.C. 552a(e)(4)(I) (the requirement to describe the categories of record sources).* To the extent that this subsection is interpreted to require a more detailed description regarding the record sources in this system than has been published in the **Federal Register**, exemption from this provision is necessary to protect the sources of law enforcement and intelligence information and to protect the privacy and safety of witnesses and informants and others who provide information to FRTIB or as part of the Thrift Savings Plan (TSP). Further, because records used to complete personnel investigations, investigate and prosecute allegations of fraud and forgery against participant accounts, pursue legal claims, pursue internal investigations of harassment or hostile work environment allegations, or investigate and prosecute allegations of insider threats could come from any source, it is not possible to know every category in advance in order to list them all in FRTIB's accompanying SORN. Some record source categories may not be appropriate to make public in the SORN if, for example, revealing them could enable individuals to discover investigative techniques and devise ways to bypass them to evade detection and apprehension.

• *5 U.S.C. 552a(f) (the requirement to promulgate rules to implement provisions of the Privacy Act).* To the extent that this subsection is interpreted to require agency rules addressing the aforementioned exempted requirements, exemption from this provision is also necessary to protect the sources of law enforcement and intelligence information and to protect the privacy and safety of witnesses and informants and others who provide information to FRTIB or as part of the TSP.

Regulatory Flexibility Act

FRTIB certifies that this proposed regulation will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*). This rulemaking does not impose a requirement for small businesses to report or keep records on any of the requirements contained in this proposed rule. The exemptions to the Privacy Act apply to individuals, and individuals are not covered entities under the Regulatory Flexibility Act.

Paperwork Reduction Act

I certify that these proposed regulations do not require additional reporting under the criteria of the Paperwork Reduction Act.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 602, 632, 653, 1501 1571, the effects of this proposed regulation on state, local, and tribal governments and the private sector have been assessed. This proposed regulation will not compel the expenditure in any one year of $100 million or more by state, local, and tribal governments, in the aggregate, or by the private sector. Therefore, a statement under § 1532 is not required.

List of Subjects in 5 CFR Part 1630

Privacy.

Ravindra Deo,

Executive Director, Federal Retirement Thrift Investment Board.

Accordingly, FRTIB proposes to amend 5 CFR part 1630 as follows:

PART 1630—PRIVACY ACT REGULATIONS

■ 1. The authority citation for part 1630 continues to read as follows:

Authority: 5 U.S.C. 552a.

■ 2. Amend § 1630.15 by revising paragraph (b) to read as follows:

§ 1630.15 Exemptions.

* * * * *

(b) Those designated systems of records which are exempt from the requirements of subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), (I); and (f) of the Privacy Act, 5 U.S.C. 552a, include FRTIB–2, Personnel Security Investigation Files; FRTIB–13, Fraud and Forgery Records; FRTIB–14, FRTIB Legal Case Files; FRTIB–15, Internal Investigations of Harassment and Hostile Work Environment Allegations; and FRTIB–23, Insider Threat Program Records.

* * * * *

[FR Doc. 2021–16435 Filed 8–12–21; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 925

[Doc. No.: AMS–SC–21–0049; SC21–925–2 PR]

Amendments to the Marketing Order of Grapes Grown in a Southeastern California

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This rule invites comments on proposed amendments to Marketing Order No. 925, which regulates the handling of grapes grown in a designated area of southeastern California. Proposed amendments would change the California Desert

Grape Administrative Committee's (Committee) size, and its quorum and voting requirements.

DATES: Comments must be received by October 12, 2021.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; or submitted to internet: *https://www.regulations.gov*. All comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *https://www.regulations.gov*. All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Pushpa Kathir, Marketing Specialist, or Matthew Pavone, Chief, Rulemaking Services Branch, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, *MarketOrderComment@usda.gov*.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, or Email: *Richard.Lower@usda.gov*.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes amendments to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposal is issued under Marketing Order No. 925, as amended (7 CFR part 925), regulating the handling of grapes grown in a designated area of southeastern California. Part 925 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of grape producers and handlers operating within the area of production, and a public member.

Section 8c(17) of the Act (7 U.S.C 608c(17)) and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR part 900) authorize amendment of the Order through this informal rulemaking action. The Agricultural Marketing Service (AMS) will consider comments received in response to this proposed rule and, based on all the information available, will determine if the Order amendment is warranted. If AMS determines amendment of the Order is warranted, a subsequent proposed rule and notice of referendum would be issued and producers would be allowed to vote for or against the proposed amendments. AMS would then issue a final rule effectuating any amendments approved by producers in the referendum.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 12866 and 13563. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

In addition, this proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. AMS has determined this proposed rule is unlikely to have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

This proposal has also been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule shall not be deemed to preclude, preempt, or supersede any State program covering grapes grown in a designated area of Southeastern California.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 8c(15)(A) of the Act (7 U.S.C. 608(15)(A)), any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed no later than 20 days after the date of entry of the ruling.

Section 1504 of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) (Pub. L. 110–246) amended section 8c(17) of the Act, which in turn required the addition of supplemental rules of practice to 7 CFR part 900 (73 FR 49307; August 21, 2008). The amendment of section 8c(17) of the Act and supplemental rules of practice authorize the use of informal rulemaking (5 U.S.C. 553) to amend Federal fruit, vegetable, and nut marketing agreements and orders. USDA may use informal rulemaking to amend marketing orders depending upon the nature and complexity of proposed amendments, potential regulatory and economic impacts on affected entities, and any other relevant matters.

AMS has considered these factors and has determined that amendments proposed herein are not unduly complex and the nature of proposed amendments is appropriate for utilizing the informal rulemaking process to amend the Order. A discussion of the potential regulatory and economic impacts on affected entities is discussed later in the ''Initial Regulatory Flexibility Analysis'' section of this proposed rule.

The Committee unanimously recommended amendments following deliberations at the public meeting held on April 13, 2021. Proposals would amend the Order by changing the Committee's size, as well as its quorum and voting requirements.

Proposal 1—Reduce Committee Size

§ 925.20 provides that the Committee consists of 12 members and, for each member of the Committee, there must be an alternate who has the same qualifications as the member. This proposal would amend § 925.20 by reducing the size of the Committee from 12 to 10 members. The requirement that

each member has an alternate with the same qualifications as the member would remain unchanged. Four members and their alternates would be producers, officers, or employees of producers (producer members). Four members and their alternates would be handlers, officers, or employees of handlers (handler members). One member and alternate would be either a producer, handler, or officer or employee thereof. One member and alternate would represent the public.

Since promulgation of the Order in 1980, the California table grape industry has seen reductions of about 55% of its producers and 58% of registered handlers. Natural industry consolidation and land development pressure have also contributed to this decline. Decreasing the Committee's size from 12 members to 10 members would make Committee membership more reflective of today's industry and enable the Committee to fill all its member positions without difficulty.

Proposal 2—Revise Quorum and Voting Requirements

Currently, § 925.30 states that eight members of the Committee shall constitute a quorum, and any action of the committee shall require at least eight concurring votes.

The proposed change would modify § 925.30 to allow six members to constitute a quorum including at a minimum one producer member and one handler member, with six concurring votes required to pass any motion or approve any Committee action. The Committee is experiencing difficulties filling all seats and obtaining a quorum at meetings to conduct business activities. Adjusting current requirements would enable the Committee to operate fully mitigating the risk of not establishing a quorum during scheduled meetings and not having the required votes to pass any action. These changes would help to streamline the Committee's operations and increase its effectiveness.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be unduly or disproportionately burdened.

Small agricultural producers have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of no more than $1,000,000. Small agricultural service firms (handlers) are defined as those with annual receipts of no more than $30,000,000.

Proposed amendments to the California desert grape marketing order would reduce the number of member and alternate seats on the California Desert Grape Administrative Committee from 12 to 10 and reduce quorum and voting requirements from 8 to 6 members. These amendments are necessary to reflect the industry's consolidation. Since the promulgation of the marketing order in 1980, the California desert grape industry has lost roughly 55 percent of its producers and 58 percent of the registered handlers.

The Committee reports that there are 21 producers and 10 handlers of table grapes in the marketing order production region. The Committee packout reports show that average annual packout for 2018 through 2020 was 3.2127 million 18-pound containers, equivalent to 28,914 tons. The 3-year average of California fresh table grape prices was $1,267 per ton. Multiplying quantity times price yields an annual average crop value estimate of $36.634 million. Dividing the average crop value estimate by the number of producers (21) yields an average crop value per producer of $1.744 million, moderately larger than the SBA small farm size threshold of $1,000,000. Therefore, using the estimated prices, packout volume, and number of producers, and assuming a normal bell-curve distribution of receipts among producers, AMS estimates the majority of producers would qualify as large businesses under the SBA definition.

Dividing the average crop value of $36.634 million by the number of handers (10) yields a per-handler estimate of $3.663 million, well below the SBA small business threshold of $30,000,000 in annual receipts. However, that computation measures handler annual receipts using producer-level crop value data, since AMS is unable to locate an estimate of a hander margin. A range of handler margin estimates would be 30 to 40 percent above the grower price. Applying those two percentages, a range of handler annual receipts estimates would be $4.8 to $5.1 million, still well below $30,000,000. Therefore, using these estimated prices, utilization volume, handler margin estimates and number of handlers, and assuming a normal bell-curve distribution of receipts among handlers, AMS estimates that the majority of handlers would meet the SBA definition of small businesses.

AMS has determined that these proposed amendments would not have a significant impact on a substantial number of small businesses. Rather, large and small entities alike would be expected to benefit from the Committee's improved ability to address important issues of interest to all on a timely basis. The proposed reduction in the number of seats on the Committee, and the reduced quorum and voting requirements, would not require any significant changes in producer or handler business operations, and no significant industry educational effort would be needed. Producers and handlers, large and small alike, would incur no additional costs. No small businesses would be unduly or disproportionately burdened.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0189, Fruit Crops. No changes in those requirements are necessary because of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large California table grape handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public-sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this action.

The Committee's meetings are widely publicized throughout the southeastern California table grape production area. All interested persons are invited to attend the meeting and encouraged to participate in Committee deliberations on all issues. Like all Committee meetings, the April 13, 2021 meeting was public, and all entities, both large and small, were encouraged to express their views on the proposals.

Interested persons are invited to submit comments on the proposed amendments to the Order, including comments on the regulatory and information collection impacts of this action on small businesses.

Following analysis of any comments received on the amendments in this proposed rule, AMS will evaluate all available information and determine whether to proceed. If appropriate, a proposed rule and notice of referendum would be issued, and producers would be provided the opportunity to vote for or against the proposed amendments. Information about the referendum, including dates and voter eligibility requirements, would be published in a future issue of the **Federal Register**. A final rule would then be issued to effectuate any amendments favored by producers participating in the referendum.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

General Findings

Findings hereinafter set forth are supplementary to findings and determinations that were previously made in connection with the issuance of Marketing Order 925; and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

1. Marketing Order 925, as hereby proposed to be amended, and all terms and conditions thereof, would tend to effectuate the declared policy of the Act;

2. Marketing Order 925, as hereby proposed to be amended, regulates the handling of grapes grown in southeastern California and is applicable only to persons in respective classes of commercial and industrial activity specified in the Order;

3. Marketing Order 925, as hereby proposed to be amended, is limited in application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several marketing orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

4. Marketing Order 925, as hereby proposed to be amended, prescribes, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of grapes produced or packed in the production area; and

5. All handling of grapes produced or packed in the production area, as defined in Marketing Order 925, is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

A 60-day comment period is provided to allow interested persons to respond to these proposals. Any comments received on amendments proposed in this rule will be analyzed, and if AMS determines to proceed based on all the information presented, a producer referendum would be conducted to determine producer support for the proposed amendments. If appropriate, a final rule would then be issued to effectuate the amendments favored by producers participating in the referendum.

List of Subjects in 7 CFR Part 925

Grapes, Marketing agreements, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, 7 CFR part 925 is proposed to be amended as follows:

PART 925—GRAPES GROWN IN A DESIGNATED AREA OF SOUTHEASTERN CALIFORNIA.

■ 1. The authority citation for 7 CFR part 925 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In § 925.20, revise paragraph (a) to read as follows:

§ 925.20 Establishment and membership.

(a) There is hereby established a California Desert Grape Committee consisting of 10 members, each of whom shall have an alternate who shall have the same qualifications as the member. Four members and their alternates shall be producers, officers or employees of producers (producer members). Four members and their alternates shall be handlers, or officers or employees of handlers (handler members). One member and alternate shall be either a producer or handler, or an officer or employee thereof. One member and alternate shall represent the public.

* * * * *

■ 3. In § 925.30, revise paragraph (a) to read as follows:

§ 925.30 Procedure.

(a) Six members of the committee shall constitute a quorum, including at a minimum one producer representative and one handler representative, and any action of the committee shall require at least six concurring votes;

* * * * *

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–17233 Filed 8–12–21; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 930

[Doc. No. AMS–SC21–0026; SC21–930–1 PR]

Tart Cherries Grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin; Changes to Reporting Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Cherry Industry Administrative Board to revise reporting requirements prescribed under the Federal marketing order regulating the handling of tart cherries. This action would modify reporting requirements to include information necessary to determine the portion of total inventory that is greater than five years old.

DATES: Comments must be received by September 13, 2021.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be submitted via the internet at: *http://www.regulations.gov.* All comments should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this proposed rule will be included in the record and the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Thomas F. Nalepa, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or email: *Thomas.Nalepa@usda.gov* or *Christian.Nissen@usda.gov.*

Small businesses may request information on complying with this

regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes an amendment to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Agreement and Order No. 930, (7 CFR part 930), regulating the handling of tart cherries produced in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin. Part 930 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Cherry Industry Administrative Board (Board or CIAB) locally administers the Order and is comprised of producers and handlers of tart cherries operating within the production area, and a public member.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 12866 and 13563. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. Agricultural Marketing Service (AMS) has determined that this proposed rule is unlikely to have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

This proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. Agricultural Marketing Service (AMS) has determined that this proposed rule is unlikely to have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This action would revise the reporting requirements to include the sales and inventory information necessary to segregate between inventory that is five years old from inventory is less than five years old. This modification would allow the industry to better estimate how much inventory on-hand is still marketable and help ensure relevant inventory information is available when considering volume restrictions. This proposal was unanimously recommended by the Board at its February 25, 2021 meeting.

Section 930.70 of the Order provides, in part, authority to require handlers to submit reports of inventory. Section 930.70 further provides, with the approval of the Secretary, authority for the Board to collect other such information from handlers as needed to perform its duties. This proposed rule would utilize this authority to establish a new § 930.170 under the rules and regulations of the Order. This new section would codify existing inventory reporting requirements and require handlers of tart cherries to annually report inventory that exceeds five years of age.

During Board meetings held on June 25, 2020 and January 14, 2021, the Board received industry feedback about enhancing tart cherry inventory transparency and developing a clearer understanding of the age of product in inventory. In these discussions, several members expressed concern that some of the inventory currently being reported may be product beyond its saleable date, which could create a misleading view of the actual amount of tart cherries available for market.

Currently, handlers submit inventory reports four times per year for reporting periods ending November 30, February 28, May 31, and June 30, with reports for those periods due on December 10, March 10, June 10, and July 10, respectively. This information is submitted on CIAB Form 3 (Sales/Inventory Report) as previously approved by OMB and assigned OMB No. 0581–0177. The report includes information on the type, form, and the amount of product, but does not include data regarding the age of products in inventory. The Board agreed that existing reporting requirements may limit their knowledge of the industry's on-hand tart cherry inventory and formed a subcommittee to review inventory reporting requirements.

The Board reviewed the subcommittee findings at the January 14, 2021, meeting, and expressed support for the subcommittee's recommendation to adjust reporting requirements to account for inventory greater than five years old. The Board noted a five-year inventory cutoff date was appropriate because this period would sufficiently accommodate lifespans of nearly all existing products likely to be inventoried. Board members agreed having this additional information regarding the age of inventory would be beneficial.

The Order includes the authority for establishing volume regulation, and one element considered during those discussions is the amount of tart cherries available in inventory. The regulated season runs from July 1 through June 30. The current reporting aggregates the industry's inventory data and does not separately track older inventory, and this compilation could provide an incomplete view of the industry's marketable inventory. By segregating the accounting of inventory older than five years, the Board would have more precise information regarding inventory when discussing market issues.

As part of their discussions, the Board also provided clarifying information on how to calculate inventory age for reporting purposes. To determine product age, the date used would either be the date of harvest and processing or date of remanufacturing. Board members emphasized the starting point for calculating inventory age would be reset if the inventory were remanufactured into a new product.

For example, if a handler was completing their routine inventory report on May 31, 2021, any tart cherries harvested in 2014 or earlier would be considered over five years old. Although cherries harvested in 2014 would be considered part of the 2014–15 harvest year, based on the date they were harvested and processed, they would be greater than five years old for reporting purposes by the end of May 2021. If cherries harvested in 2014 were remanufactured into another product, the date of remanufacturing would become the date used for calculating the age for inventory purposes. The Board stated this is the same dating procedure as used for calculating the age of cherries held in reserve under volume regulation. Using these dates, inventory older than five years would be reported each May on the modified report.

Several members commented the age of inventory is already recorded by handlers as part of their normal business activities, and as a result, this requirement would not be overly burdensome. Members further expressed the separate reporting of inventory over five years old would, at most, require a few extra minutes of a handler's time and would only be required once annually.

Consequently, the Board voted to add a section to the inventory report to include the total volume of inventory over five years old. The Board recommended including this information on the inventory report for the reporting period ending May 31 due on June 10. The Board agreed this was the appropriate time to have the information available as this report would be used to develop the industry inventory data when the Board meets in June to consider the need to establish a volume control recommendation for the coming season.

This proposed rule would add sales and inventory report requirements to administrative provisions under the Order and would require handlers to report inventory older than five years. These reporting requirements would be added in a new § 930.170 and would include information on the handler submitting the form; the reporting period; beginning inventory for each product; the amount packed for each product; sales; information on transfers of product between handlers, including the name of the selling handler, name of the receiving handler, and form type, number of units; information on product repacked or remanufactured during the reporting period, including form type and number of units of source products and form type and number of units of end products; and information on the amount of ending inventory for each product, including the amount of ending inventory for each product over five years old. Only the May 31 report would require handlers to record amounts of inventories over five years old.

This information would support the industry's ability to make marketing decisions by providing more descriptive information than currently available when evaluating the need for volume regulation. Besides providing important information for industry reports regarding sales and inventory, this action would also help ensure compliance with this reporting requirement by including it in the rules and regulations under the Order.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 450 producers of tart cherries in the regulated area and approximately 40 handlers who are subject to the Order. Small agricultural growers are defined by the Small Business Administration as those having annual receipts less than $1,000,000, and small agricultural service firms are defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

According to information from the National Agricultural Statistics Service (NASS) and Board data, the average annual grower price for tart cherries during the 2019–2020 season was approximately $0.15 per pound. With total utilization at 236.34 million pounds, the total 2019–20 crop value is estimated at $35.45 million (236.34 million pounds times $0.15). Dividing the crop value by the estimated number of producers (450) yields an estimated average receipt per producer of $78,778. This is well below the SBA threshold for small producers.

A free-on-board (FOB) price of $0.82 per pound for processed tart cherries was derived from USDA's 2020 purchases of dried tart cherries at an average price of $4.11 per pound. The dried cherry price was converted to a raw product equivalent price at an industry recognized ratio of five to one. Based on utilization, this price represents a good estimate of the price for processed cherries. Multiplying this FOB price ($0.82) by total utilization of 236.34 million pounds results in an estimated handler-level tart cherry value of $193.8 million. Dividing this figure by the number of handlers (40) yields estimated average annual handler receipts of $4.84 million, which is below the SBA threshold for small agricultural service firms. Assuming a normal distribution, the majority of producers and handlers of tart cherries may be classified as small entities.

This proposed rule would add the sales and inventory report requirements to the administrative provisions under the Order and would require handlers to report inventory older than five years. This proposed rule would establish a new § 930.170 under the rules and regulations of the Order. The authority for this proposed action is provided in § 930.70 of the Order.

AMS anticipates that this proposed rule would impose minimal, if any, additional costs on handlers or growers, regardless of their size. This action would impose a small increase in the reporting burden for each tart cherry handler. However, because handlers currently maintain data about the age of their inventory in the regular course of business, they should be able to readily access this information. Consequently, any additional costs associated with this change would be minimal (not significant) and apply equally to all handlers.

This proposed action should also benefit the entire industry by providing more precise information on tart cherry product in inventory. This information would provide accurate information regarding available inventory and help with marketing and planning for the industry. Further, having these requirements codified under the rules and regulations would also benefit compliance enforcement of this reporting requirement. The benefits of this rule are expected to be equally available to all tart cherry growers and handlers, regardless of their size.

The Board discussed other alternatives to this proposed action, including reporting inventory older than three years for the purposes of classifying the age of inventory, reporting the age of inventory quarterly, and leaving the current reporting requirements unchanged. When discussing alternatives, the Board concluded a three-year timeframe would not sufficiently cover the normal lifespan of all products held in inventory. The Board also commented that quarterly reporting of older inventory was unnecessary because this information would be most useful at the end of the season, prior to making annual volume restriction recommendations. Therefore, the alternatives were rejected.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0177, Tart Cherries Grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin. This proposed rule would require changes to the Board's existing CIAB Form 3. However, changes are minor and the currently approved burden for the form would be minimally increased by the proposed changes. The revised form has been submitted to OMB for approval.

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Further, Board meetings are widely publicized throughout the tart cherry industry. Meetings are public and virtual or in a hybrid style with participants having a choice whether to attend in person or virtually. All interested persons are invited to attend meetings and participate in Board deliberations on all issues. Board meetings on June 25, 2020, January 14, 2021, and February 25, 2021, were each conducted via videoconference. All entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including regulatory and information collection impacts of this proposed action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 930

Marketing agreements, Reporting and recordkeeping requirements, Tart cherries.

For reasons set forth in the preamble, 7 CFR part 930 is proposed to be amended as follows:

PART 930—TART CHERRIES GROWN IN THE STATES OF MICHIGAN, NEW YORK, PENNSYLVANIA, OREGON, UTAH, WASHINGTON, AND WISCONSIN

■ 1. The authority citation for 7 CFR part 930 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Add § 930.170 to read as follows:

§ 930.170 Sales and Inventory Report.

(a) Handlers shall submit to the Board a sales and inventory report for the reporting period ending November 30, February 28, May 31, and June 30 of each crop year. Handlers shall file such reports by the tenth day of the month following the reporting period, December 10, March 10, June 10, and July 10, respectively. Should the filing due date fall on a Saturday, Sunday, or federal holiday, reports are due by the first business day following the due date. Such reports shall be reported to the Board on CIAB Form 3 and include:

(1) The name, address, telephone number, and identifying number of the handler;

(2) The reporting period covered by the report;

(3) The form, type, and unit size for each product;

(4) The total beginning of year inventory for each product;

(5) The packed amount for each product;

(6) Total inter-handler transfers, and total volume repackaged or remanufactured for each product, year-to-date;

(7) Total sales outside the industry for each product, year-to-date;

(8) The amount of ending inventory for each product, year-to-date;

(9) List of inter-handler transfers, both in and out, during the reporting period including:

(i) Name of the selling handler;

(ii) Name of the receiving handler; and

(iii) Form, type, number of units.

(10) List of repacks and remanufactures during the reporting period including:

(i) Form, type, and number of units of source products; and

(ii) Form, type, and number of units of end products.

(b) The amount of inventory for each product over 5 years old shall be reported annually on the sales and inventory report for the reporting period ending May 31. Product age is based on the crop year in which the current product was processed or remanufactured.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–17234 Filed 8–12–21; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2021–0108]

RIN 3150–AK64

List of Approved Spent Fuel Storage Casks: TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System, Certificate of Compliance No. 1029, Renewal of Initial Certificate and Amendment Nos. 1, 3, and 4

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its spent fuel storage regulations by revising the TN Americas, LLC, Standardized Advanced NUHOMS® Horizontal Modular Storage System listing within the ''List of approved spent fuel storage casks'' to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 3, and 4 of Certificate of Compliance No. 1029. The renewal of the initial certificate and Amendment Nos. 1, 3, and 4 revises the certificate of compliance's conditions and technical

specifications to address aging management activities related to the structures, systems, and components of the dry storage system to ensure that these will maintain their intended functions during the period of extended storage operations.

DATES: Submit comments by September 13, 2021. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2021–0108, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christopher Markley, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6293, email: *Christopher.Markley@nrc.gov* and Irene Wu, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–1951, email: *Irene.Wu@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Obtaining Information and Submitting Comments
II. Rulemaking Procedure
III. Background
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V. Availability of Documents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0108 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0108. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2021–0108 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on October 27, 2021. However, if the NRC receives any significant adverse comment by September 13, 2021, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For a more detailed discussion of the proposed rule changes and associated analyses, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the

Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on January 6, 2003 (68 FR 463), that approved the Standardized Advanced NUHOMS® Horizontal Modular Storage System design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1029.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Availability of Documents

The documents identified in the following table are available to interested persons, as indicated.

Document	ADAMS Accession No.
TN Americas, LLC Renewal Application for the Standardized NUHOMS® Horizontal Modular Storage System Certificate of Compliance No. 1029, dated May 22, 2019.	ML19148A484 (package).
TN Americas, LLC Response to Request for Supplemental Information for the Technical Review of the Application for Certificate of Compliance No. 1029, dated December 4, 2019.	ML19338E132.
TN Americas, LLC Response to Request for Additional Information of the Application for Renewal of the Certificate of Compliance No. 1029, dated May 28, 2020.	ML20192A127.
User Need Memorandum for Rulemaking for Certificate of Compliance Renewal, Initial Issue (Amendment Number 0), Amendment Numbers 1, 3, and 4 to Standardized Advanced NUHOMS® Horizontal Modular Storage System.	ML21067A166.
Preliminary Safety Evaluation Report for the Standardized Advanced NUHOMS® Horizontal Modular Storage System Certificate of Compliance Renewal.	ML21067A167.
Proposed Certificate of Compliance No. 1029, Renewed Initial Certificate	ML21067A168.
Proposed Technical Specifications, Attachment A, Certificate of Compliance No. 1029, Renewed Initial Certificate	ML21067A169.
Proposed Certificate of Compliance No. 1029, Renewed Amendment No. 1	ML21067A170.
Proposed Technical Specifications, Attachment A, Certificate of Compliance No. 1029, Renewed Amendment No. 1.	ML21067A171.
Proposed Certificate of Compliance No. 1029, Renewed Amendment No. 3	ML21067A172.
Proposed Technical Specifications, Attachment A, Certificate of Compliance No. 1029, Renewed Amendment No. 3.	ML21067A173.
Proposed Certificate of Compliance No. 1029, Renewed Amendment No. 4	ML21067A174.
Proposed Technical Specifications, Attachment A, Certificate of Compliance No. 1029, Renewed Amendment No. 4.	ML21067A175.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2021–0108.

Dated: August 6, 2021.

For the Nuclear Regulatory Commission.

Daniel H. Dorman,

Acting Executive Director for Operations.

[FR Doc. 2021–17194 Filed 8–12–21; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0653; Project Identifier AD–2021–00170–R]

RIN 2120–AA64

Airworthiness Directives; MD Helicopters Inc. (MDHI) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for MD Helicopters Inc. (MDHI), Model 369D, 369E, 369F, 369FF, 369H, 369HE, 369HM, 369HS, 500N, and 600N helicopters. This proposed AD was prompted by a report of a spiral crack in the pilot-to-copilot tail rotor torque tube (torque tube). This proposed AD would require a one-time visual and recurring borescope inspections of the torque tube and depending on the results, removing the torque tube from service. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 27, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address between 9 a.m. and 5 p.m.,

Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact MD Helicopters, Inc., Attn: Customer Support Division, 4555 E McDowell Rd., Mail Stop M615, Mesa, AZ 85215–9734; telephone (800) 388–3378; fax (480) 346–6813; or at *https://www.mdhelicopters.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0653; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Payman Soltani, Aerospace Engineer, Airframe Section, Los Angeles ACO Branch, Compliance & Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (562) 627–5313; email *payman.soltani@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0653; Project Identifier AD–2021–00170–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Payman Soltani, Aerospace Engineer, Airframe Section, Los Angeles ACO Branch, Compliance & Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (562) 627–5313; email *payman.soltani@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA proposes to adopt a new AD for MDHI Model 369D, 369E, 369F, 369FF, 369H, 369HE, 369HM, 369HS, 500N, and 600N helicopters. This proposed AD would require a one-time visual and recurring borescope inspections of the torque tube and depending on the results, removing the torque tube from service. This proposed AD was prompted by a report of a spiral crack in the torque tube that appears to have originated from a hole where the tail rotor torque tube control fitting attaches to the torque tube on a Model 369FF helicopter. This crack resulted in increased left pedal movement and subsequent reduced directional control pedal authority. Other model helicopters are affected due to design similarity. This condition, if not addressed, could result in failure of the torque tube, loss of tail rotor control, and subsequent loss of control of the helicopter.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of these same type designs.

Related Service Information Under 1 CFR Part 51

The FAA reviewed MD Helicopters Service Bulletin SB369D–229R2 for Model 369D helicopters, SB369E–129R2 for Model 369E helicopters, SB369F–119R2 for Model 369F and 369FF helicopters, SB369H–263R2 for Model 369H, 369HE, 369HM, and 369HS helicopters, SB500N–066R2 for Model 500N helicopters, and SB600N–080R2 for Model 600N helicopters, each dated March 24, 2021 (Revision 2). These service bulletins are co-published as one document. Revision 2 of this service information specifies procedures for a one-time visual inspection and recurring borescope inspections, completing a Service Operation Report, and returning a removed torque tube to an authorized service center or MDHI.

Other Related Service Information

The FAA also reviewed MD Helicopters Service Bulletin SB369H–263, SB369D–229, SB369E–129, SB369F–119, SB500N–066, and SB600N–080, each dated January 30, 2020 (initial issuance), and MD Helicopters Service Bulletin SB369H–263R1, SB369D–229R1, SB369E–129R1, SB369F–119R1, SB500N–066R1, and SB600N–080R1, each dated May, 15 2020 (Revision 1). The initial issuance and Revision 1 of this service information specify the same procedures as Revision 2 of this service information, except Revision 1 clarified the torque value to apply to the nut and Revision 2 deletes Method 2 of the Accomplishment Instructions and adds a recurring 300-hour borescope inspection of the torque tube.

Proposed AD Requirements in This NPRM

This proposed AD would initially require visually inspecting the torque tube exterior using a flashlight and mirror and borescope inspecting the interface of the torque tube and bushing segments for a crack, elongation, and other damage, which may be indicated by any corrosion, pitting, crazing, dents, dings, displacement of material at the bolt hole edge, or fretting of the hole. Thereafter, this proposed AD would require repeating the borescope inspection. If there is a crack, elongation, or other damage, this proposed AD would require removing the torque tube from service.

Differences Between This Proposed AD and the Service Information

For helicopters that have accumulated 600 or less total hours time-in-service (TIS), Revision 2 of the service information specifies an initial compliance time of during the next 100-hour inspection, whereas this proposed AD would require initial actions within 100 hours TIS after the effective date of this AD instead. For helicopters that have accumulated more than 600 total

hours TIS, Revision 2 of the service information specifies initial a compliance time of within 5 hours of flight time, whereas this proposed AD would require initial actions within 5 hours TIS or 30 days after the effective date of this AD, whichever occurs later, instead.

Revision 2 of the service information specifies returning a removed torque tube, whereas this proposed AD would require removing the torque tube from service instead. Revision 2 of the service information specifies completing a Service Operation Report, whereas this proposed AD does not include that requirement.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 58 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

Visually inspecting the torque tube would take a minimal amount of time. Borescope inspecting the torque tube would take about 1 work-hour for an estimated cost of $85 per helicopter and $4,930 for the U.S. fleet, per inspection cycle.

If required, replacing the torque tube would take about 5 work-hours and parts would cost about $983 for an estimated cost of $1,408 per helicopter.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

MD Helicopters Inc. (MDHI): Docket No. FAA–2021–0653; Project Identifier AD–2021–00170–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 27, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to MD Helicopters Inc. (MDHI) Model 369D, 369E, 369F, 369FF, 369H, 369HE, 369HM, 369HS, 500N, and 600N helicopters, certificated in any category, with pilot-to-copilot tail rotor torque tube (torque tube) part number 369H7531–9/–11/–13, installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6720, Tail Rotor Control System.

(e) Unsafe Condition

This AD was prompted by a report of a spiral crack in the torque tube. The FAA is issuing this AD to prevent failure of a torque tube. The unsafe condition, if not addressed, could result in loss of tail rotor control and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Using a flashlight and mirror, visually inspect the exterior of the torque tube at the interface of the torque tube and bushing segments, and borescope inspect the interior of the torque tube at the interface of the torque tube and bushing segments for a crack, elongation, and other damage, which may be indicated by any corrosion, pitting, crazing, dents, dings, displacement of material at the bolt hole edge, or fretting of the hole by following the Accomplishment Instructions, paragraphs 2.A.(1). through (3).(a)., of MD Helicopters Service Bulletin SB369H–263R2, SB369D–229R2, SB369E–129R2, SB369F–119R2, SB500N–066R2, or SB600N–080R2, each dated March 24, 2021, as applicable to your model helicopter, as follows:

Note 1 to paragraph (g)(1): Scaling of the inner diameter primer or paint may be an indication of a crack.

(i) For helicopters that have accumulated 600 or less total hours time-in-service (TIS), within 100 hours TIS after the effective date of this AD.

(ii) For helicopters that have accumulated more than 600 total hours TIS, within 5 hours TIS or 30 days after the effective date of this AD, whichever occurs later.

Note 2 to paragraph (g)(1)(ii): It is advised to limit flights with increased, excessive, or rapid pedal movements before the first instance of the actions required by paragraph (g)(1)(ii) are accomplished.

(iii) If there is a crack, elongation, or other damage, before further flight, remove the torque tube from service.

(2) Thereafter following paragraph (g)(1) of this AD, at intervals not to exceed 300 hours TIS, borescope inspect the interior of the torque tube at the interface of the torque tube and bushing segments as required by paragraph (g)(1) of this AD. If there is a crack, elongation, or other damage, before further flight, remove the torque tube from service.

(h) Credit for Previous Actions

You may take credit for the instance of the actions required by paragraphs (g)(1)(i) or (ii) of this AD if you performed corresponding actions before the effective date of this AD using MD Helicopters Service Bulletin SB369H–263, SB369D–229, SB369E–129, SB369F–119, SB500N–066, or SB600N–080, each dated January 30, 2020, as applicable to your model helicopter, or MD Helicopters Service Bulletin SB369H–263R1, SB369D–229R1, SB369E–129R1, SB369F–119R1, SB500N–066R1, or SB600N–080R1, each dated May, 15 2020, as applicable to your model helicopter.

(i) No Reporting Requirement

Although MD Helicopters Service Bulletin SB369H–263R2, SB369D–229R2, SB369E–129R2, SB369F–119R2, SB500N–066R2, and SB600N–080R2, each dated March 24, 2021, specify to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, information may be emailed to: *9-ANM-LAACO-AMOC-REQUESTS@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For more information about this AD, contact Payman Soltani, Aerospace Engineer, Airframe Section, Los Angeles ACO Branch, Compliance & Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (562) 627–5313; email *payman.soltani@faa.gov*.

(2) For service information identified in this AD, contact MD Helicopters, Inc., Attn: Customer Support Division, 4555 E McDowell Rd., Mail Stop M615, Mesa, AZ 85215–9734; telephone (800) 388–3378; fax (480) 346–6813; or at *https://www.mdhelicopters.com.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Issued on August 2, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–17032 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0662; Project Identifier MCAI–2021–00031–E]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Rolls-Royce Deutschland Ltd & Co KG (RRD) Trent 1000 model turbofan engines. This proposed AD was prompted by reports of high levels of wear on the seal fins on a small number of certain high-pressure turbine triple seals. This proposed AD would require manual deactivation of the modulated air system (MAS) control valves. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 27, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: +44 (0)1332 242424; fax: +44 (0)1332 249936; website: *https://www.rolls-royce.com/contact-us.aspx.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0662; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; fax: (781) 238–7199; email: *kevin.m.clark@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0662; Project Identifier MCAI–2021–00031–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2021–0009, dated January 8, 2021 (referred to after this as ''the MCAI''), to

address the unsafe condition on these products. The MCAI states:

The Modulated Air System (MAS) optimises cooling air, extracted from the compressor, where full flow is not required at cruise conditions. It is only active during cruise. Recently, occurrences have been reported of finding high levels of wear on the seal fins on a small number of high pressure turbine triple seals, Part Number FW3448. The effect on the secondary air system was conservatively assessed due to the resultant increased turbine cooling air leakage, which changes the cooling flow around the intermediate pressure (IP) turbine disc.

This condition, if not corrected, could lead to temperature increase at the IP turbine disc rim when the MAS is active, possibly resulting in IP turbine disc failure and high energy debris release, with consequent damage to, and reduced control of, the aeroplane. To address this potential unsafe condition, Rolls-Royce has issued the NMSB, providing instructions to manually 'lock-out' (deactivate) the MAS control valves.

For the reason described above, this [EASA] AD requires to deactivate the MAS control valves. This [EASA] AD also specifies that the Master Minimum Equipment List (MMEL) item for 'MAS inoperative', which has a limit of 120 days, does not apply when the system is manually deactivated.

You may obtain further information by examining the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0662.

FAA's Determination

This product has been approved by EASA and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Community, EASA has notified the FAA of the unsafe condition described in the MCAI and service information. The FAA is issuing this AD because the agency evaluated all the relevant information provided by EASA and has determined that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Rolls-Royce Alert Non-Modification Service Bulletin (NMSB) Trent 1000 75–AK642, Initial Issue, dated November 30, 2020. This service information specifies procedures for deactivating the MAS control valves. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Proposed AD Requirements in This NPRM

This proposed AD would require manual deactivation of the MAS control valves. Manual deactivation of the MAS control valves changes the engine to an approved configuration that will produce engine indicating and crew alerting system (EICAS) status messages that do not indicate inoperative (failed) equipment. Consequently, when these messages are displayed, the operator's existing FAA-approved minimum equipment list (MEL) instructions and limitations, including the 120-day operation limitation, do not apply.

Interim Action

The FAA considers that this proposed AD would be an interim action. If final action is later identified, the FAA might consider additional rulemaking.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 4 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Deactivate the MAS control valves	2 work-hours × $85 per hour = $170	$0	$170	$680

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce plc): Docket No. FAA–2021–0662; Project Identifier MCAI–2021–00031–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 27, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (RRD) (Type Certificate previously held by Rolls-Royce plc) Trent 1000–AE3, Trent 1000–CE3, Trent 1000–D3, Trent 1000–G3, Trent 1000–H3, Trent 1000–J3, Trent 1000–K3, Trent 1000–L3, Trent 1000–M3, Trent 1000–N3, Trent 1000–P3, Trent 1000–Q3, and Trent 1000–R3 model turbofan engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by reports of high levels of wear on the seal fins on a small number of certain high-pressure turbine (HPT) triple seals. The FAA is issuing this AD to prevent wear on the seal fins on the affected HPT triple seals. The unsafe condition, if not addressed, could result in failure of the intermediate-pressure turbine disk, loss of engine thrust control, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

Within the compliance time specified in figure 1 to paragraph (g) of this AD, deactivate the modulated air system (MAS) control valves using the Accomplishment Instructions, paragraphs 3.A.(6) and 3.A.(7), of Rolls-Royce Alert Non-Modification Service Bulletin (NMSB) Trent 1000 75–AK642, Initial Issue, dated November 30, 2020.

Note 1 to paragraph (g): Deactivation of the MAS control valves on an engine required by paragraph (g) of this AD changes the engine to an approved configuration that will produce engine indicating and crew alerting system (EICAS) status messages ''ENG MAS VALVE L/R'' and ''ENG MAS SYS TEST L/R.'' Since MAS is purposely disabled after compliance with paragraph (g) of this AD, these status messages do not indicate inoperative (failed) equipment and, consequently, the operator's existing FAA-approved minimum equipment list (MEL) instructions and limitations, including the 120-day operation limitation, do not apply.

Note 2 to paragraph (g): Deactivation of the MAS control valves on an engine as required by paragraph (g) of this AD does not produce the EICAS status message ''ENG MAS VALVE SENSOR L/R.'' Consequently, when this EICAS message displays, it remains indicative of inoperative equipment, even if the MAS has been disabled as required by paragraph (g) of this AD. As a result, the corresponding MEL instructions and limitations apply whenever the EICAS status message ''ENG MAS VALVE SENSOR L/R'' is displayed.

FIGURE 1 TO PARAGRAPH (g)—COMPLIANCE TIME

MAS deactivation option	Compliance time, whichever occurs later after the effective date of this AD, A or B
A	Within 50 engine flight cycles (FCs) since new.
B	Within 30 days or 100 FCs, whichever occurs first.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in Related Information. Information may be emailed to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Related Information

(1) For more information about this AD, contact Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; fax: (781) 238–7199; email: *kevin.m.clark@faa.gov.*

(2) For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: +44 (0)1332 242424; fax: +44 (0)1332 249936; website: *https://www.rolls-royce.com/contact-us.aspx.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Issued on August 5, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–17071 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0659; Project Identifier 2018–SW–112–AD]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Leonardo S.p.a. Model A109A, A109A II, A109C, A109E, A109K2, A109S, AW109SP, A119, and AW119 MKII helicopters. This proposed AD was prompted by a report of damage to a rigid connecting link (rod), and loosening of the nut on the upper rod end. This proposed AD would require a visual inspection of the affected rods for damage, cracks, or abnormal play, and corrective actions if necessary, as specified in a European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 27, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For EASA material that is proposed for IBR in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel,

Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0659.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0659; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (516) 228–7323; email: *Darren.Gassetto@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0659; Project Identifier 2018–SW–112–AD'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (516) 228–7323; email: *Darren.Gassetto@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0280, dated December 17, 2018 (EASA AD 2018–0280), to correct an unsafe condition for Leonardo S.p.a. (formerly Finmeccanica S.p.A., AgustaWestland S.p.A., Agusta S.p.A.; and AgustaWestland Philadelphia Corporation, formerly Agusta Aerospace Corporation) Model A109A, A109A II, A109C, A109E, A109K2, A109S, A109LUH, AW109SP, A119, and AW119 MKII helicopters. Model A109LUH helicopters are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those helicopters in the applicability.

This proposed AD was prompted by a report of damage to a rod, and loosening of the nut on the upper rod end. The FAA is proposing this AD to address damage to the rod, and loosening of the nut on the upper rod end, which could result in failure of the rod, possibly resulting in reduced control of the helicopter. See EASA AD 2018–0280 for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2018–0280 requires a visual inspection of the affected rods for damage, cracks, or evidence of abnormal play, and, depending on findings, any applicable corrective actions (which include replacing damaged or cracked connecting links and actions to address abnormal play).

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

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2018–0280, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2018–0280 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2018–0280 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2018–0280 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2018–0280. Service information required by EASA AD 2018–0280 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0659 after the FAA final rule is published.

Interim Action

The FAA considers this proposed AD would be an interim action. The inspection reports that are required by this AD will enable the manufacturer to obtain better insight into the nature, cause, and extent of the cracking, and eventually to develop final action to address the unsafe condition. Once final action has been identified, the FAA might consider further rulemaking.

Costs of Compliance

The FAA estimates that this proposed AD affects 291 helicopters of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$24,735

The FAA estimates that it would take about 1 work-hour per product to comply with the proposed reporting requirement in this proposed AD. The average labor rate is $85 per hour. Based on these figures, the FAA estimates the cost of reporting the inspection results on U.S. operators to be $24,735, or $85 per product.

The FAA estimates the following costs to do any necessary on-condition replacements that would be required based on the results of any required inspections. The FAA has no way of determining the number of aircraft that might need these on-condition replacements:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
3 work-hours × $85 per hour = $255	Up to $2,351	Up to $2,606.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to take approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Leonardo S.p.a.: Docket No. FAA–2021–0659; Project Identifier 2018–SW–112–AD.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 27, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model A109A, A109A II, A109C, A109E, A109K2, A109S, AW109SP, A119, and AW119 MKII helicopters, certificated in any category, with an affected part as identified in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2018–0280, dated December 17, 2018 (EASA AD 2018–0280).

(d) Subject

Joint Aircraft Service Component (JASC) Codes: 6700, Rotorcraft Flight Control; 6730, Rotorcraft Servo System.

(e) Unsafe Condition

This AD was prompted by a report of damage to a rigid connecting link (rod), and loosening of the nut on the upper rod end. The FAA is issuing this AD to address damage to the rod, and loosening of the nut on the upper rod end. The unsafe condition, if not addressed, could result in failure of the rod, possibly resulting in reduced control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2018–0280.

(h) Exceptions to EASA AD 2018–0280

(1) Where EASA AD 2018–0280 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2018–0280 requires compliance from its effective date, this AD requires using the effective date of this AD.

(3) Where EASA AD 2018–0280 specifies action if ''any discrepancy'' is found, for this AD, discrepancies include damage, cracks, and evidence of abnormal play.

(4) Where the service information specified in EASA AD 2018–0280 specifies to ''replace the damaged connecting link'', for this AD, if any damage or cracks are found, remove the rod from service.

(5) Where the service information specified in EASA AD 2018–0280 specifies to ''contact Leonardo Helicopters'' if abnormal play is detected, for this AD if any abnormal play is detected, corrective action must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Leonardo S.p.a.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(6) Where EASA AD 2018–0280 requires reporting inspection results to Leonardo S.p.a. within 14 days after the effective date of EASA AD 2018–0280, this AD requires reporting inspection results at the applicable time in paragraph (h)(6)(i) or (ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 14 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 14 days after the effective date of this AD.

(7) This AD does not require the ''Remarks'' section of EASA AD 2018–0280.

(i) Special Flight Permit

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For EASA AD 2018–0280, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet *www.easa.europa.eu*. You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0659.

(2) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (516) 228–7323; email: *Darren.Gassetto@faa.gov.*

Issued on August 4, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–17046 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0660; Project Identifier AD–2021–00398–T]

RIN 2120–AA64

Airworthiness Directives; Learjet Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Learjet Inc. Model 45 airplanes. This proposed AD was prompted by a report of a fuel leak due to a cracked fuel line between the engine fuel control and the engine fuel flow meter. This proposed AD would require replacing the existing fuel flow meter bracket assembly with a redesigned bracket assembly and reporting information to the FAA. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 27, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Learjet Inc., One Learjet Way, Wichita, KS 67209; phone: (316) 946–2000; email: *ac.ict@aero.bombardier.com;* website: *https://businessaircraft.bombardier.com/en/aircraft/Learjet.html.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by

searching for and locating Docket No. FAA–2021–0660; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: James Galstad, Aviation Safety Engineer, Wichita ACO Branch, FAA, 1801 S Airport Road, Wichita, KS 67209; phone: (316) 946–4135; email: *james.galstad@faa.gov* or *Wichita-COS@faa.gov;* or Thomas Teplik, Aviation Safety Engineer, Wichita ACO Branch, FAA, 1801 S Airport Road, Wichita, KS 67209; phone: (316) 946–4196; email: *thomas.teplik@faa.gov* or *Wichita-COS@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0660; Project Identifier AD–2021–00398–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to James Galstad, Aviation Safety Engineer, or Thomas Teplik, Aviation Safety Engineer, Wichita ACO Branch, FAA, 1801 S Airport Road, Wichita, KS 67209. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA received a report of a fuel leak due to a cracked fuel line between the engine fuel control and the engine fuel flow meter on a Learjet Model 45 (Learjet 45) airplane. There are four different Model 45 configurations: Model 45 (Learjet 40), Model 45 (Learjet 45), Model 45 (Learjet 70), and Model 45 (Learjet 75). They all are susceptible to cracked fuel lines with possible fuel leakage because the fuel flow meter bracket and fuel line is common to each model. Further analysis of the fleet of all the 45 models revealed similar failures in this area including the following: 16 fuel line failures, 2 instances of multiple inlet attaching bolts breaking, 9 leaking fuel controls, a broken gearbox strut, 4 cracked No. 6 bearing oil supply lines, and 7 cracked engine oil tanks. The FAA evaluated the flammable fluid leaks and broken parts and determined that they may have resulted from vibration.

Following the above report and analysis, Learjet designed a new engine fuel flow meter bracket and incorporated it during production. The unsafe condition, if not addressed, could result in an engine installation fire, which could progress to an uncontrolled fire and consequent loss of control of the airplane.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Bombardier Learjet 40 Service Bulletin (SB) SB 40–73–01, Revision 1, Bombardier Learjet 45 SB 45–73–2, Revision 1, Bombardier Learjet 70 SB 70–73–01, Revision 1, and Bombardier Learjet 75 SB 75–73–01, Revision 2, all dated January 9, 2017. This service information specifies procedures for replacing the existing fuel flow meter bracket assembly with a redesigned bracket assembly with pad fuel flow meter that has an increased material thickness. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described, except as discussed under ''Differences Between this Proposed AD and the Service Information.''

Differences Between This Proposed AD and the Service Information

This proposed AD would require reporting certain maintenance information to the FAA, where the service information does not. The information provided in the reports would be related to contributing factors that the FAA found showed a correlation between the reported engine fan vibration levels and the cracking fuel line between engine fuel control and the engine fuel flow meter and a correlation between the cracking fuel line and a certain batch of fan disks. In addition, the FAA found that a contributing factor could be the susceptibility of the fuel flow meter bracket assembly and the susceptibility of the bracket assembly with pad fuel flow meter to the vibration induced. The requested reporting information would allow the FAA to determine whether further rulemaking action would be necessary to mitigate the unsafe condition.

Also, the effectivity of Bombardier Learjet 45 SB 45–73–2, Revision 1, dated January 9, 2017, begins with serial number 45–005. This proposed AD would also apply to airplane serial numbers 45–002 through 45–004 because, although these three airplanes are not currently in service, they are subject to the unsafe condition. Thus, it is necessary to include them in the event they are returned to service.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 443 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacing the bracket assembly	4.5 work-hours × $85 per hour = $382.50	$3,895	$4,277.50	$1,894,932.50
Reporting and reviewing logbooks	9 work-hours × $85 per hour = $765	Not Applicable	765	338,895

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to take approximately 9 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship tween the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Learjet Inc.: Docket No. FAA–2021–0660; Project Identifier AD–2021–00398–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 27, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Learjet Inc. Model 45 (Learjet 40), Model 45 (Learjet 45), Model 45 (Learjet 70), and Model 45 (Learjet 75) airplanes, serial numbers 45–002 through 45–556 and 45–2001 through 45–2146, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 7100, Powerplant System.

(e) Unsafe Condition

This AD was prompted by a report of a fuel leak due to a cracked fuel line between the engine fuel control and the engine fuel flow meter. The FAA is issuing this AD to prevent cracking and failures. The unsafe condition, if not addressed, could result in an engine installation fire, which could progress to an uncontrolled fire and consequent loss of control of the airplane.

(f) Compliance

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

(g) Reporting Requirement

Within 60 days after the effective date of this AD, report the following information, where available, to the Wichita ACO Branch via email at *james.galstad@faa.gov, thomas.teplik@faa.gov,* and *Wichita-COS@faa.gov;* or by mail to Wichita ACO Branch, Attn: James Galstad/Thomas Teplik, 1801 S Airport Road, Room 100, Wichita, KS 67209.

(1) Name of the owner; the address of the owner; name of the organization doing the actions required by this AD; the date the actions were completed; the name of the person submitting the report; the address, telephone number, and email of the person submitting the report.

(2) The fan vibration levels that have been recorded in the airplane and engine maintenance records since November 1, 2019. Include the airplane and engine serial numbers.

(3) The date of each vibration level recorded and the associated hours time-in-service for the airplane and each engine.

(4) For each fan vibration level reported, include:

(i) Whether molybdenum coating for the fan was applied per Temporary Revision 72–494, dated August 15, 2017 (or as subsequently incorporated into the engine's Inspection/Repair Manual TFE731 (ATA Number 72–IR–02).

(ii) If molybdenum coating was applied using a different process than Temporary Revision 72–494, dated August 15, 2017 (or as subsequently incorporated into the engine's Inspection/Repair Manual TFE731 (ATA Number 72–IR–02), report the process by which the molybdenum coating was applied and the revision level of the document defining the application process for the molybdenum coating.

Note 1 to paragraph (g)(4): Temporary Revision 72–494, dated August 15, 2017, specifies applying a dry film lubricant on the mating surfaces of the fan hub and the fan blades. The lubricating solid for this dry film lubricant is molybdenum disulfide, which is referred to in this AD as molybdenum coating.

(5) For each fan vibration level reported, the fan hub serial number and hours time-in-service for this fan hub.

(6) Installation date and service bulletin (SB) revision level for the installation of the bracket assembly with pad fuel flow meter and hose if installed before the effective date of this AD.

(7) Any failures of the bracket assembly with pad fuel flow meter and hose installed in accordance with any SB listed in paragraph (h) or any prior revision of these SBs.

(8) Installation date and SB revision level used for installation of the fuel control screws within the engine fuel control in accordance with Honeywell SB TFE731–73–5146

(9) Any failures of fuel control screws after compliance with Honeywell SB TFE731–73–5146.

(h) Replacement

Within 12 months after the effective date of this AD or 750 hours time-in-service after the effective date of this AD, whichever occurs first, replace the engine fuel flow meter bracket in accordance with the Accomplishment Instructions, paragraphs 3.A through 3.C, of the following Bombardier SB applicable to your airplane model.

(1) Bombardier Learjet 40 SB 40–73–01, Revision 1, dated January 9, 2017.

(2) Bombardier Learjet 45 SB 45–73–2 Revision 1, dated January 9, 2017.

(3) Bombardier Learjet 70 SB 70–73–01 Revision 1, dated January 9, 2017.

(4) Bombardier Learjet 75 SB 75–73–01, Revision 2, dated January 9, 2017.

(i) Credit for Previous Actions

(1) This paragraph provides credit for the actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Bombardier Learjet 40 SB 40–73–01, Basic Issue, Bombardier Learjet 45 Service Bulletin SB 45–73–2, Basic Issue, Bombardier Learjet 70 SB 70–73–01, Basic Issue, or Bombardier Learjet 75 SB 75–73–01, Basic Issue, all dated October 3, 2016, or Bombardier Learjet 75 SB 75–73–01, Revision 1, dated October 10, 2016.

(2) To take credit for any previous action, you must comply with paragraph (g) of this AD within 60 days after the effective date of this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in Related Information.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For more information about this AD, contact James Galstad, Aviation Safety Engineer, Wichita ACO Branch, FAA, 1801 S Airport Road, Wichita, KS 67209; phone: (316) 946–4135; email: *james.galstad@faa.gov* or *Wichita-COS@faa.gov;* or Thomas Teplik, Aviation Safety Engineer, Wichita ACO Branch, FAA, 1801 S Airport Road, Wichita, KS 67209; phone: (316) 946–4196; email: *thomas.teplik@faa.gov.*

(2) For service information identified in this AD, contact Learjet Inc., One Learjet Way, Wichita, KS, 67209; phone: (316) 946–2000; email: *ac.ict@aero.bombardier.com;* website: *https://businessaircraft.bombardier.com/en/aircraft/Learjet.html.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued on August 5, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–17044 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0663; Project Identifier MCAI–2020–01618–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2016–17–12, which applies to all Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2016–17–12 requires inspecting certain trimmable horizontal stabilizer actuators (THSAs) to determine the number of total flight cycles the THSA has accumulated, and replacing the THSA if necessary. Since the FAA issued AD 2016–17–12, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 27, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For EASA material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* For Airbus service information identified in this proposed AD, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *https://www.airbus.com.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0663. For the UTC Aerospace Systems material identified in this proposed AD that will not be incorporated by reference, contact Collins Aerospace, Product Support Department 13, Avenue de L'Eguillette—Saint-Ouen L'Aumone, Boite Postale 7186 95056 Cergy Pontoise Cedex, France; telephone 1–877–808–7575; email *crc@collins.com;* internet *https://www.collinsaerospace.com/support.*

Examining the AD Docket

You may examine the AD docket on the internet at *https://*

www.regulations.gov by searching for and locating Docket No. FAA–2021–0663; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *sanjay.ralhan@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0663; Project Identifier MCAI–2020–01618–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *sanjay.ralhan@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2016–17–12, Amendment 39–18625 (81 FR 58823, August 26, 2016) (AD 2016–17–12), for all Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2016–17–12 requires inspecting certain THSAs to determine the number of total flight cycles the THSA has accumulated, and replacing the THSA if necessary. The FAA issued AD 2016–17–12 to address premature wear of the carbon friction disks on the no-back brake (NBB) of the THSA, which could lead to reduced braking efficiency in certain load conditions, and, in conjunction with the inability of the power gear train to keep the ball screw in its last commanded position, could result in uncommanded movements of the trimmable horizontal stabilizer and loss of control of the airplane.

Actions Since AD 2016–17–12 Was Issued

Since the FAA issued AD 2016–17–12, new investigations determined that the compliance time for removal from service and replacement of certain THSA NBB disks must be reduced. This task was required by AD 2016–17–12, and the task and newly reduced compliance time have now been incorporated into Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS) Part 4 Variation 7.1, dated October 5, 2020. The FAA has therefore determined that new or more restrictive airworthiness limitations are necessary.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0270, dated December 7, 2020 (EASA AD 2020–0270) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, and –171N airplanes; Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

Airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after October 5, 2020, must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet. However, Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS) Part 4 Variation 7.1 specifies that replacements can be accomplished in accordance with certain service information, while this proposed AD would require accomplishing those replacements in accordance with certain service information. To ensure all maintenance or inspection programs incorporate the revised task, including the revised replacement requirements, this proposed AD would therefore require all operators to revise their existing maintenance or inspection program to include either the revised task including the revised provisions for replacement, or the revised provisions for replacement, depending on when the original airworthiness certificate or original export certificate of airworthiness was issued.

EASA AD 2020–0270 specifies that it requires a task (limitation) already required by EASA AD 2020–0034, dated February 25, 2020 (which corresponds to FAA AD 2020–21–10, Amendment 39–21283 (85 FR 65190, October 15, 2020) (AD 2020–21–10)) and invalidates (terminates) prior instructions for that task. This proposed AD would terminate the ALS limitation for task 274000–00004–1–E for the THSAs, as required by paragraph (i) of AD 2020–21–10, for Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, and –153N airplanes; Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes; with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 7, 2019, only.

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is proposing this AD to address premature wear of the carbon friction disks on the NBB of the THSA, which could lead to reduced braking efficiency in certain load conditions, and, in conjunction with the inability of the power gear train to keep the ball screw in its last commanded position, could result in uncommanded movements of the trimmable horizontal stabilizer and loss of control of the airplane. See the MCAI for additional background information.

Model A320–216 Airplanes

The Airbus SAS Model A320–216 was U.S. type certificated on December 19, 2016. Before that date, any EASA ADs that affected Model A320–216 airplanes were included in the U.S. type certificate as part of the Required Airworthiness Actions List (RAAL). One or more Model A320–216 airplanes have subsequently been placed on the U.S. Register, and will now be included in FAA AD actions. For Model A320–216 airplanes, the requirements that correspond to AD 2016–17–12 were mandated by the MCAI via the RAAL. Although that RAAL requirement is still in effect, for continuity and clarity the FAA has identified Model A320–216 airplanes in paragraph (c) of this proposed AD; the MCAI that is specified in paragraph (l) in this proposed AD includes restated requirements, which would therefore apply to those airplanes.

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0270 describes new or more restrictive airworthiness limitations for airplane structures and safe life limits.

Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS) Part 4 Variation 7.1, dated October 5, 2020, describes a task for removal from service and replacement of certain THSA NBB disks.

This proposed AD would also require Airbus Service Bulletin A320–27–1242, Revision 01, dated February 4, 2016, which the Director of the Federal Register approved for incorporation by reference as of September 30, 2016 (81 FR 58823, August 26, 2016).

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

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA has evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Proposed AD Requirements

This proposed AD would retain the requirements of AD 2016–17–12. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, which are specified in EASA AD 2020–0270 described previously, as proposed for incorporation by reference. Any differences with EASA AD 2020–0270 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (p)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use certain civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2020–0270 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2020–0270 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2020–0270 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2020–0270. Service information required by EASA AD 2020–0270 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0663 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in the AMOCs paragraph under ''Other FAA Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative actions or intervals.

Costs of Compliance

The FAA estimates that this proposed AD affects 1,630 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS *

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2016–17–12 (959 airplanes)	1 work-hour × $85 per hour = $85 ..	$0	$85	$81,515

* Table does not include estimated costs for reporting/revising the existing maintenance or inspection program.

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new proposed actions to be $7,650 (90 work-hours × $85 per work-hour).

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
21 work-hours × $85 per hour = $1,785	$26,500	$28,285

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2016–17–12, Amendment 39–18625 (81 FR 58823, August 26, 2016); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2021–0663; Project Identifier MCAI–2020–01618–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 27, 2021.

(b) Affected ADs

(1) This AD replaces AD 2016–17–12, Amendment 39–18625 (81 FR 58823, August 26, 2016) (AD 2016–17–12).

(2) This AD affects AD 2020–21–10, Amendment 39–21283 (85 FR 65190, October 15, 2020) (AD 2020–21–10).

(c) Applicability

This AD applies to all Airbus SAS airplanes, certificated in any category, identified in paragraphs (c)(1) through (7) of this AD.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(5) Model A319–151N, –153N, and –171N airplanes.

(6) Model A320–251N, –252N, –253N, –271N, –272N, and –273N airplanes.

(7) Model A321–251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks; 27, Flight Controls.

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address premature wear of the carbon friction disks on the no-back brake (NBB) of the trimmable horizontal stabilizer actuator (THSA), which could lead to reduced braking efficiency in certain load conditions, and, in conjunction with the inability of the power gear train to keep the ball screw in its last commanded position, could result in uncommanded movements of the trimmable horizontal stabilizer and loss of control of the airplane.

(f) Compliance

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

(g) Retained Inspection To Determine THSA Part Number and Accumulated Total Flight Cycles, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: No later than each date specified in paragraphs (g)(1) through (5) of this AD, inspect the THSA to determine if it has a part number (P/N) 47145–(XXX), and, if any THSA P/N 47145–(XXX) is found, determine the total number of flight cycles accumulated since the THSA's first installation on an airplane, or since the most recent NBB replacement, whichever is later. A review of airplane delivery or maintenance records is acceptable in lieu of this inspection if the part number of the THSA can be conclusively determined from that review. In case maintenance records concerning the most recent NBB disk replacement are unavailable or incomplete, the total flight cycles accumulated since first installation of the THSA on an airplane apply. Accomplishing the maintenance or inspection program revision required by paragraph (l) of this AD terminates the requirements of this paragraph.

(1) *As of September 30, 2016 (the effective date of AD 2016–17–12):* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 40,000 total flight cycles.

(2) *As of December 31, 2016:* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 36,000 total flight cycles.

(3) *As of December 31, 2017:* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 33,600 total flight cycles.

(4) *As of December 31, 2018:* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 31,600 total flight cycles.

(5) *As of December 31, 2019:* The THSA flight-cycle limit (since first installation on an airplane, or since the most recent NBB replacement, whichever is later) is 30,000 total flight cycles.

(h) Retained Replacements, With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: For airplanes with any THSA P/N 47145–(XXX), do the replacements required by paragraphs (h)(1) and (2) of this AD. Accomplishing the maintenance or inspection program revision required by paragraph (l) of this AD terminates the requirements of this paragraph.

(1) No later than each date specified in paragraphs (g)(1) through (5) of this AD, replace all THSA that have reached or exceeded on each date the corresponding number of flight cycles specified in paragraphs (g)(1) through (5) of this AD. Do the replacement in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1242, Revision 01, dated February 4, 2016. Affected THSAs must be replaced with serviceable THSAs.

(2) As of each date specified in paragraphs (g)(1) through (5) of this AD, and before exceeding the flight cycle limit corresponding to each date, as applicable: Replace each THSA with a serviceable THSA, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1242, Revision 01, dated February 4, 2016.

(i) Retained Definition of Serviceable THSA, With No Changes

This paragraph restates the definition of paragraph (i) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: For the purposes of this AD, a serviceable THSA is a THSA that has not exceeded the applicable flight-cycle limits, as specified paragraphs (g)(1) through (5) of this AD, since first installation of the THSA on an airplane or since last NBB replacement, whichever is later.

Note 1 to paragraph (i): Guidance for NBB disk replacement can be found in UTC Aerospace Systems Service Bulletin 47145–27–17, Revision 1, dated July 21, 2015.

(j) Retained Parts Installation Limitation, With No Changes

This paragraph restates the provisions of paragraph (j) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: As of each date specified in paragraphs (g)(1) through (5) of this AD, as applicable, only installation of a serviceable THSA P/N 47145–(XXX) is allowed on an airplane. Accomplishing the maintenance or inspection program revision required by paragraph (l) of this AD terminates the requirements of this paragraph.

(k) Retained Credit for Previous Actions, With No Changes

This paragraph restates the requirements of paragraph (k) of AD 2016–17–12, with no changes. For airplanes identified in paragraphs (c)(1) through (4) of this AD: This paragraph provides credit for actions required by paragraph (h) of this AD, if those actions were performed before September 30, 2016 (the effective date of AD 2016–17–12), using Airbus Service Bulletin A320–27–1242, dated February 9, 2015.

(l) New Maintenance or Inspection Program Revision

(1) For the airplanes identified in paragraph (c) of this AD with an original airworthiness certificate or original export certificate of airworthiness issued on or before October 5, 2020, except as specified in paragraph (m) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0270, dated December 7, 2020 (EASA AD 2020–0270). Accomplishing the maintenance or inspection program revision required by this paragraph terminates the requirements of paragraphs (g), (h), and (j) of this AD.

(2) For the airplanes identified in paragraph (c) of this AD with an original airworthiness certificate or original export certificate of airworthiness issued after October 5, 2020, revise the existing maintenance or inspection program, as applicable, to incorporate the provision specified in paragraph (m)(7) of this AD.

(m) Exceptions to EASA AD 2020–0270

(1) Where EASA AD 2020–0270 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2020–0270 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2020–0270 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2020–0270 is at the applicable ''thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2020–0270, or within 90 days after the effective date of this AD, whichever occurs later.

(5) The provisions specified in paragraph (4) of EASA AD 2020–0270 do not apply to this AD.

(6) The ''Remarks'' section of EASA AD 2020–0270 does not apply to this AD.

(7) For all airplanes identified in paragraph (c) of this AD: Where Note 1 in the service information referenced in EASA AD 2020–0270 specifies ''NBB carbon disc replacement can be accomplished in accordance with SB A320–27–1242 or VSB 47145–27–17,'' for this AD use ''NBB carbon disk replacement must be accomplished in accordance with SB A320–27–1242.''

(n) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (l) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2020–0270.

(o) Terminating Action for Certain Requirements of AD 2020–21–10

Accomplishing the actions required by this AD terminates the ALS limitation task 274000–00004–1–E for the THSA, as required by paragraph (i) of AD 2020–21–10, for Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, and –153N airplanes; Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N,

–271NX, –272N, and –272NX airplanes; with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 7, 2019, only.

(p) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (q)(4) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(ii) AMOCs approved previously for AD 2016–17–12 are approved as AMOCs for the corresponding provisions of EASA AD 2020–0270 that are required by paragraph (l) of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (p)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(q) Related Information

(1) For EASA AD 2020–0270, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(2) For Airbus service information identified in this proposed AD, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *https://www.airbus.com.*

(3) For UTC Aerospace Systems material identified in this proposed AD, contact Collins Aerospace, Product Support Department 13, Avenue de L'Eguillette—Saint-Ouen L'Aumone, Boite Postale 7186 95056 Cergy Pontoise Cedex, France; telephone 1–877–808–7575; email *crc@collins.com;* internet *https://www.collinsaerospace.com/support.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0663.

(5) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *sanjay.ralhan@faa.gov.*

Issued on August 5, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–17091 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0637; Airspace Docket No. 21–ANM–31]

RIN 2120–AA66

Proposed Establishment Class E Airspace; Portland-Troutdale Airport, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace, designated as an extension to a Class D or Class E surface area, at Portland-Troutdale Airport, Portland, OR. This action also proposes numerous administrative updates to the Class D and Class E2 text headers and airspace descriptions. This action would ensure the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Comments must be received on or before September 27, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0637; Airspace Docket No. 21–ANM–31, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S. 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish Class E airspace at Portland-Troutdale Airport, Portland, OR, to support IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related

aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–0637; Airspace Docket No. 21–ANM–31''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S. 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by establishing Class E airspace at Portland-Troutdale Airport, Portland, OR. The additional airspace is designed to properly contain IFR aircraft descending below 1,000 feet above the surface on the RNAV (GPS)-A approach.

This action also proposes numerous administrative updates to the Class D and Class E2 text headers and airspace descriptions. The first line of the text headers should be updated from ''ANM OR D Portland-Troutdale, OR'' to ''ANM OR D Portland, OR'', Portland is the official city for the airport. The second line of the text headers should be updated from ''Portland-Troutdale Airport, Troutdale, OR'' to ''Portland-Troutdale Airport, OR'', this line should only list the airport name and state. A fourth and fifth line of text should be added to the headers. The lines should read ''Portland International Airport, OR'' and ''(Lat. 45°35′19″ N, long. 112°35′49″ W)', respectively. The additional lines are necessary because the airspace descriptions contain exclusionary language for Portland Airport's Class C airspace area. The term Airport/Facility Directory'' in the last sentence of the Class D airspace description is outdated and should be corrected to ''Chart Supplement.'' The Class E2 airspace area is not in use continuously, to accurately describe the airspace, the following sentences should be added to the description. ''This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.''

Class D, Class E2, and Class E4 airspace designations are published in paragraphs 5000, 6002, and 6004, respectively, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

ANM OR D Portland, OR [Amended]

Portland-Troutdale Airport, OR
(Lat. 45°32′58″ N, long. 122°24′05″ W)
Portland International Airport, OR
(Lat. 45°35′19″ N, long. 112°35′49″ W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4-mile radius of the Portland-Troutdale Airport, excluding the portion within Portland International Airport's Class C airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area.

* * * * *

ANM OR E2 Portland, OR [Amended]

Portland-Troutdale Airport, OR
(Lat. 45°32′58″ N, long. 122°24′05″ W)
Portland International Airport, OR
(Lat. 45°35′19″ N, long. 112°35′49″ W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4-mile radius of the Portland-Troutdale Airport, excluding the portion within the Portland International Airport's Class C airspace area. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ANM OR E4 Portland, OR [New]

Portland-Troutdale Airport, OR
(Lat. 45°32′58″ N, long. 122°24′05″ W)

That airspace extending upward from the surface within 2.3 miles each side of the 212° bearing from the airport extending from a 4-mile radius of the airport to 10.4 miles to the southwest of the airport.

Issued in Des Moines, Washington, on August 5, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–17109 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0633; Airspace Docket No. 21–ANM–22]

RIN 2120–AA66

Proposed Modification and Establishment of Class E airspace; Frank Wiley Field Airport, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace, designated as an extension to a Class D or Class E surface area, at Frank Wiley Field Airport, Miles City, MT. This action also proposes to remove the Class E airspace extending upward from 1,200 feet above the surface. Additionally, the action proposes an administrative update to the Class E2 and E5 text headers. This action would ensure the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Comments must be received on or before September 27, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0633; Airspace Docket No. 21–ANM–22, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S. 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish and modify Class E airspace at Frank Wiley Field Airport, Miles City, MT, to support IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–0633; Airspace Docket No. 21–ANM–22''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S. 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace

Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by establishing Class E airspace, designated as an extension to a Class D or Class E surface area, at Frank Wiley Field Airport, Miles City, MT. The FAA proposes to amend the VOR RWY 4 approach and the amendment will relocate the point where aircraft descend below 1,000 feet above the surface from ''3.35 miles'' to ''10.8 miles southwest of the airport.'' The additional Class E airspace will ensure the containment of IFR aircraft flying the approach.

This action also proposes to remove the Class E airspace extending upward from 1,200 feet above the surface. This airspace area is wholly contained with the Glasgow en route airspace and duplication is not necessary.

Additionally, the action proposes an administrative update to the Class E2 and E5 text headers. The city name should not appear in the second line of the text header, and the term ''Airport'' should be added. This line of text should be changed from ''Miles City, Frank Wiley Field, MT'' to ''Frank Wiley Field Airport, MT''.

Class E2, E4, and E5 airspace designations are published in paragraphs 6002, 6004, and 6005, respectively, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area.

* * * * *

ANM MT E2 Miles City, MT [Amended]

Frank Wiley Field Airport, MT
(Lat. 46°25′41″ N., long. 105°53′10″ W.)

That airspace extending upward from the surface within a 5-mile radius of the airport.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ANM MT E4 Miles City, MT [New]

Frank Wiley Field Airport, MT
(Lat. 46°25′41″ N., long. 105°53′10″ W.)

That airspace extending upward from the surface within 2.4 miles each side of the 225° bearing from the airport extending from the Class E2's 5-mile radius of the airport to 10.8 miles southwest of the airport.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM MT E5 Miles City, MT [Amended]

Frank Wiley Field Airport, MT
(Lat. 46°25′41″ N., long. 105°53′10″ W.)

That airspace extending upward from 700 feet above the surface within an 8-mile radius of the airport.

Issued in Des Moines, Washington, on August 5, 2021.

B. G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–17108 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0632; Airspace Docket No. 21–ASW–11]

RIN 2120–AA66

Proposed Amendment of J–8 and V–140, and Establishment of T–422 in the Vicinity of Kingfisher, OK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Jet Route J–8 and VHF Omnidirectional Range (VOR) Federal airway V–140, and establish Area Navigation (RNAV) route T–422 in the vicinity of Kingfisher, OK. The Air Traffic Service (ATS) route modifications are necessary due to the planned decommissioning of the VOR portion of the Kingfisher, OK, VOR/Tactical Air Navigation (VORTAC) navigational aid (NAVAID) which provides navigational guidance for portions of J–8 and V–140. The VOR portion of the VORTAC is being decommissioned as part of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before September 27, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0632; Airspace Docket No. 21–ASW–11 at the beginning of your comments. You

may also submit comments through the internet at *https://www.regulations.gov.* FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2021–0632; Airspace Docket No. 21–ASW–11) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–0632; Airspace Docket No. 21–ASW–11.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX, 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning decommissioning activities for the VOR portion of the Kingfisher, OK, VORTAC in May 2022. The VOR portion of the Kingfisher, OK, VORTAC is a candidate VOR identified for discontinuance by the FAA's VOR MON program and listed in the final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

Although the VOR portion of the Kingfisher VORTAC is planned for decommissioning, the co-located DME portion of the NAVAID is being retained to support Performance Based Navigation (PBN) procedures.

The existing ATS route dependencies to the Kingfisher, OK, VORTAC NAVAID are Jet Route J–8 and VOR Federal airway V–140. With the planned decommissioning of the VOR portion of the Kingfisher, OK, VORTAC, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of these affected ATS routes. As such, proposed modifications to the routes would result in the creation of a gap in J–8 and the creation of two gaps in V–140.

To overcome the proposed gaps in the routes, instrument flight rules (IFR) traffic could use adjacent ATS routes, including Jet Routes J–6, J–14, J–20, J–78, and J–98 in lieu of the affected J–8 segment and VOR Federal airways V–14, V–272, V–436, and V–440 in lieu of the affected V–140 segment or receive air traffic control (ATC) radar vectors to fly through or circumnavigate the affected area. Additionally, IFR pilots equipped with RNAV capabilities could also navigate point to point using the existing fixes that will remain in place to support continued operations though the affected area. Visual flight rules (VFR) pilots who elect to navigate via the airways through the affected area could also take advantage of the adjacent VOR Federal airways or ATC services listed previously.

Further, the FAA proposes to establish an RNAV route T–422 between the Panhandle, TX, VORTAC and the Tulsa, OK, VORTAC to, in part, mitigate the proposed removal of the V–140 airway segment affected by the planned decommissioning of the Kingfisher VOR. Also, establishing T–422 would provide RNAV routing capability between the Amarillo, TX, area

eastward to the Tulsa, OK, area; as well as, support ongoing FAA NextGen efforts to transition the NAS to performance-based navigation.

Prior to this NPRM, the FAA published a rule for Docket No. FAA–2020–0654 in the **Federal Register** (85 FR 79425; December 10, 2020), amending VOR Federal airway V–140 by removing the airway segment between the London, KY, VOR/Distance Measuring Equipment (VOR/DME) and the Bluefield, WV, VOR/DME. That airway amendment, effective February 25, 2021, is included in this NPRM.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by modifying Jet Route J–8 and VOR Federal airway V–140, and establishing RNAV route T–422. The planned decommissioning of the VOR portion of the Kingfisher, OK, VORTAC has made this action necessary.

The proposed Jet route change is outlined below.

J–8: J–8 currently extends between the Needles, CA, VORTAC and the Casanova, VA, VORTAC. The FAA proposes to remove the route segment overlying the Kingfisher, OK, VORTAC between the Borger, TX, VORTAC and the Springfield, MO, VORTAC. The unaffected portions of the existing route would remain as charted.

The proposed VOR Federal airway change is outlined below.

V–140: V–140 currently extends between the Panhandle, TX, VORTAC and the London, KY, VOR/DME; and between the Bluefield, WV, VOR/DME and the Casanova, VA, VORTAC. The FAA proposes to remove the airway segment overlying the Kingfisher, OK, VORTAC between the Burns Flat, OK, VORTAC and the Tulsa, OK, VORTAC. The unaffected portions of the existing airway would remain as charted.

The proposed new RNAV T-route is outlined below.

T–422: T–422 is a proposed new route that would extend between the Panhandle, TX, VORTAC and the Tulsa, OK, VORTAC. This RNAV route would mitigate the proposed loss of the V–140 airway segment proposed to be removed (above) between the Burns Flat, OK, VORTAC and the Tulsa, OK, VORTAC and provide RNAV routing capability between the Amarillo, TX, area and the Tulsa, OK, area.

All of the NAVAID radials listed in the ATS route descriptions below are unchanged and stated in True degrees.

Jet routes are published in paragraph 2004, VOR Federal airways are published in paragraph 6010(a), and United States RNAV T-routes are published in paragraph 6011 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The ATS routes listed in this document would be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–8 [Amended]

From Needles, CA; Flagstaff, AZ; Gallup, NM; Fort Union, NM; to Borger, TX. From Springfield, MO; St Louis, MO; Louisville, KY; Charleston, WV; INT Charleston 092° and Casanova, VA, 253° radials; to Casanova.

* * * * *

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–140 [Amended]

From Panhandle, TX; to Burns Flat, OK. From Tulsa, OK; Razorback, AR; Harrison, AR; Walnut Ridge, AR; Dyersburg, TN; Nashville, TN; Livingston, TN; to London, KY. From Bluefield, WV; INT Bluefield 071° and Montebello, VA, 250° radials; Montebello; to Casanova, VA.

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T422 Panhandle, TX (PNH) to Tulsa, OK (TUL) [New]

Panhandle, TX (PNH)	VORTAC	(Lat. 35°14′06.22″ N, long. 101°41′56.51″ W)
Burns Flat, OK (BFV)	VORTAC	(Lat. 35°14′13.00″ N, long. 099°12′22.20″ W)
BISKT, OK	WP	(Lat. 35°48′18.66″ N, long. 098°00′14.73″ W)

LASTS, OK	FIX	(Lat. 35°59′45.23″ N, long. 097°16′24.76″ W)
GULLI, OK	FIX	(Lat. 36°00′43.02″ N, long. 097°08′39.63″ W)
Tulsa, OK (TUL)	VORTAC	(Lat. 36°11′46.51″ N, long. 095°47′17.13″ W)

Issued in Washington, DC, on August 4, 2021.

George Gonzalez,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2021–16968 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0634; Airspace Docket No. 21–ACE–19]

RIN 2120–AA66

Proposed Amendment of Class D and Class E Airspace; Fort Leonard Wood, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class D and Class E airspace at Waynesville-St. Robert Regional Airport Forney Field, Fort Leonard Wood, MO. The FAA is proposing this action as the result of an airspace review caused by the decommissioning of the Maples very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The name of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before September 27, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2021–0634/Airspace Docket No. 21–ACE–19 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class D airspace, the Class E airspace area designated as an extension to a Class D surface area, and the Class E airspace extending upward from 700 feet above the surface at Waynesville-St. Robert Regional Airport Forney Field, Fort Leonard Wood, MO, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–0634/Airspace Docket No. 21–ACE–19.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by:

Amending the Class D airspace at Waynesville-St. Robert Regional Airport Forney Field, Fort Leonard Wood, Mo, by updating the name (previously Waynesville Regional Airport at Forney Field) of the airport to coincide with the FAA's aeronautical database; and replacing the outdated term of ''Airport/Facility Directory'' with ''Chart Supplement'';

Amending the Class E airspace area designated as an extension to a Class D surface area at Waynesville-St. Robert Regional Airport Forney Field by removing the Buckhorn NDB and associated extensions from the airspace legal description as they are no longer needed; removing the exclusionary language as it is no longer needed; updating the name (previously Waynesville Regional Airport at Forney Field) of the airport to coincide with the FAA's aeronautical database; and replacing the outdated term of ''Airport/Facility Directory'' with ''Chart Supplement'';

And amending the Class E airspace extending upward from 700 feet above the at Waynesville-St. Robert Regional Airport Forney Field by removing the Buckhorn NDB and associated extensions from the airspace legal description as they are no longer needed; and updating the name (previously Waynesville Regional Airport at Forney Field) of the airport to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review caused by the decommissioning of the Maples VOR, which provided navigation information for the instrument procedures this airport, as part of the VOR MON Program.

Class D and E airspace designations are published in paragraph 5000, 6004, and 6005, respectively, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designation listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ACE MO D Fort Leonard Wood, MO [Amended]

Waynesville-St. Robert Regional Airport Forney Field, MO
(Lat. 37°44′30″ N, long. 92°08′27″ W)

That airspace extending upward from the surface to and including 3,700 feet MSL within a 4-mile radius of the Waynesville-St. Robert Regional Airport Forney Field. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ACE MO E4 Fort Leonard Wood, MO [Amended]

Waynesville-St. Robert Regional Airport Forney Field, MO
(Lat. 37°44′30″ N, long. 92°08′27″ W)
Forney VOR
(Lat. 37°44′33″ N, long. 92°08′20″ W)

That airspace extending upward from the surface within 2.4 miles each side of the Forney VOR 318° radial extending from the 4-mile radius of Waynesville-St. Robert Regional Airport Forney Field to 7 miles northwest of the VOR. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE MO E5 Fort Leonard Wood, MO [Amended]

Waynesville-St. Robert Regional Airport Forney Field, MO
(Lat. 37°44′30″ N, long. 92°08′27″ W)
Forney VOR
(Lat. 37°44′33″ N, long. 92°08′20″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Waynesville-St. Robert Regional Airport Forney Field and within 2.4 miles each side of the Forney VOR 318° radial extending from the 6.5-mile radius of the airport to 7 miles northwest of the VOR, excluding that airspace within the R–4501 Fort Leonard Wood, MO, Restricted Areas during the specific times they are in effect.

Issued in Fort Worth, Texas, on August 5, 2021.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–17006 Filed 8–12–21; 8:45 am]

BILLING CODE 4910–13–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2021–8; Order No. 5951]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is acknowledging a recent filing requesting the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports (Proposal Five). This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* September 15, 2021.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Proposal Five
III. Notice and Comment
IV. Ordering Paragraphs

I. Introduction

On August 4, 2021, the Postal Service filed a petition pursuant to 39 CFR 3050.11, requesting that the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports.[1] The Petition identifies the proposed analytical changes filed in this docket as Proposal Five.

[1] Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Five), August 4, 2021 (Petition). The Postal Service filed two non-public Attachments under seal with Proposal Five as part of Library Reference USPS–RM2021–8/NP1. The information is of the type provided under seal within Docket No. ACR2020, Library Reference USPS–FY20–NP2 and –NP5 in the Postal Service's FY2020 Annual Compliance Report. The Postal Service therefore incorporates by reference the Application for Non-Public Treatment of Materials contained in Attachment Two to the United States Postal Service Fiscal Year 2020 Annual Compliance Report, filed on December 29, 2020. Library Reference USPS–RM2021–8/NP1, August 4, 2021; Notice of Filing of USPS–RM2021–8/NP1 and Application for Nonpublic Treatment, August 4, 2021.

II. Proposal Five

Proposal. The Postal Service proposes to treat International surface transportation to Canada separately from the treatment of International air transportation. Petition, Proposal Five at 1. The Postal Service explains that the proposal uses additional Foreign Postal Settlement System (FPS) data to develop a distribution key to more accurately distribute outbound International surface transportation expenses to Canada (Account 53281). *Id.* After isolating International surface transportation to Canada for separate treatment, the proposal continues to use the International Air Transportation file to distribute outbound International air transportation expenses (Accounts 53201 and 53212), with a refinement to remap surface parcels to regular parcels in the distribution. *Id.* Account 53281 expenses would be isolated from the other expenses and additional FPS data would be used to distribute account 53281 expenses to international mail categories transported to Canada by surface. *Id.*

Rationale. Following information requests during the recent Annual Compliance Report process, the Postal Service reviewed its international transportation costs. *Id.* at 2. The Postal Service indicates that removing account 53281 from the current treatment that sums accounts 53201, 53212, and 53281 results in the distribution of only air expenses. The Postal Service concludes that with new surface and air treatments for accounts 53201, 53212, and 53281, and account 53286 continuing to receive its separate treatment as part of the FedEx agreement, there is no longer a need for diversion factors. *Id.*

The Postal Service notes that the International Cost and Revenue Analysis (ICRA) has traditionally described the method for calculating outbound international transportation expenses. *Id.* The Postal Service states that the proposal mostly maintains the methodology described in the Air Transportation Cost Computations, but would remove account 53281 from the benchmarking of International air transportation expenses for all countries. *Id.* at 3.

The Postal Service states that the primary subject of this proposal is the International highway costs section. *Id.* Currently, the proportions of total outbound kilograms to Canada are used to develop diversion ratios for mail types transported by surface. *Id.* at 4. The proposal would use U.S. and Canada information service center origin destination pairs by ICRA outbound mail class to replace the diversion percentages. *Id.*

The Postal Services notes that additional FPS data is used to distribute expenses for outbound surface transportation to Canada. It concludes that ''refining the treatment of air transportation costs would improve ICRA reporting by providing a finer level of mail category detail that: (1) Eliminates treating the sum of air and surface costs together, (2) eliminates the need to develop air to surface diversion factors to isolate or divert Canada surface transportation expenses, and (3) provides the basis for the distribution of surface costs using surface data and the distribution of air costs using air data.'' *Id.* at 4–5.

Impact. The Postal Service claims that the two non-public attachments accompanying the proposal show its ''modest impact,'' and indicates that both are filed under seal as part of Library Reference USPS–RM2021–8/NP1. *Id.* at 5. It concludes that the net impact on total Market Dominant and total Competitive products costs is zero. *Id.* Additional pages display the detailed impacts on Market Dominant products and Competitive products. The Postal Service concludes that, overall, the proposal would shift roughly $158,000 of attributable costs from Market Dominant to Competitive products. *Id.*

The Postal Service also indicates that the change in Total Volume Variable and Product Specific Cost in Attachment 2 reflect the International Negotiated Service Agreement (NSA) differences in Attachment 1. It concludes these show that all NSAs that were compensatory in FY 2020 would have remained so under this proposal. *Id.*

Mechanics. The Postal Service details several of the adjustments that would be made to various files by the proposal. *Id.* at 6.

III. Notice and Comment

The Commission establishes Docket No. RM2021–8 for consideration of matters raised by the Petition. More information on the Petition may be accessed via the Commission's website at *http://www.prc.gov.* Interested persons may submit comments on the Petition and Proposal Five no later than September 15, 2021. Pursuant to 39 U.S.C. 505, Jennaca D. Upperman is designated as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2021–8 for consideration of the matters raised by the Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Five), filed August 4, 2021.

2. Comments by interested persons in this proceeding are due no later than September 15, 2021.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Jennaca D. Upperman to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2021–17191 Filed 8–12–21; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–R09–OAR–2021–0426; FRL–8710–03–R9]

Designation of Areas for Air Quality Planning Purposes; California; Eastern Kern, Sacramento Metro, and Western Nevada 2015 Ozone Nonattainment Areas; Reclassification to Serious

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Clean Air Act (CAA), the Environmental Protection Agency (EPA) is proposing to grant requests by the California Air Resources Board (CARB) to reclassify three nonattainment areas in California from ''Moderate'' to ''Serious'' for the 2015 ozone national ambient air quality standards (NAAQS). These three areas are herein referred to as the Eastern Kern, Sacramento Metro, and Western Nevada nonattainment areas. In connection with the reclassification, the EPA is proposing to establish deadlines for submittal of revisions to the Eastern Kern, Sacramento Metro, and Western Nevada portions of the California state implementation plan (SIP) to meet additional requirements for Serious ozone nonattainment areas.

DATES: Comments must be received on or before September 13, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2021–0426 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ben Leers, Air Planning Office (AIR–2), EPA Region IX, (415) 947–4279, *Leers.Ben@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we'', ''us,'' and ''our'' refer to the EPA.

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  B. New Source Review and Title V Program Revisions
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I. Background

The CAA requires the EPA to establish primary and secondary NAAQS for certain pervasive pollutants that ''may reasonably be anticipated to endanger public health and welfare.'' The primary NAAQS is designed to protect public health with an adequate margin of safety, and the secondary NAAQS is designed to protect public welfare and the environment. The EPA has set NAAQS for six common air pollutants, referred to as criteria pollutants, including ozone. The NAAQS represent the air quality levels an area must meet to comply with the CAA. Ozone is a gas composed of three oxygen atoms and is created by chemical reactions between volatile organic compounds (VOC) and oxides of nitrogen (NO_X) in the atmosphere in the presence of sunlight. Ground-level ozone can harm human health and the environment. Ozone exposure has been associated with increases in susceptibility to respiratory infections, medication use by asthmatics, doctor visits, and emergency department visits and hospital admissions for individuals with respiratory disease. Ozone exposure may also contribute to premature death, especially in people with heart and lung disease.

In October 2015, the EPA strengthened the primary and secondary eight-hour ozone NAAQS from 0.075 parts per million (ppm) to 0.070 ppm (''2015 ozone NAAQS'').[1] In accordance with section 107(d) of the CAA, the EPA must designate an area ''nonattainment'' if it is violating the NAAQS or if it is contributing to a violation of the NAAQS in a nearby area. With respect to the ozone NAAQS, the EPA further classifies nonattainment areas as ''Marginal,'' ''Moderate,'' ''Serious,'' ''Severe,'' or ''Extreme,'' depending upon the ozone design value for an area.[2] As a general matter, higher classified ozone nonattainment areas are subject to a greater number of, and more stringent, CAA planning requirements than lower classified areas but are allowed more time to demonstrate attainment of the ozone NAAQS.[3]

Effective August 3, 2018, the EPA designated and classified the Eastern

[1] 80 FR 65291 (October 26, 2015).

[2] See CAA section 181(a)(1). For the 2015 ozone NAAQS, the design value at each monitoring site is the annual fourth-highest daily maximum 8-hour average ozone concentration, averaged over three years. The design value for an area is the highest design value among the monitoring sites in the area.

[3] See, generally, subpart 2 of part D of title I of the CAA.

Kern,[4] Sacramento Metro,[5] and Western Nevada[6] areas under the CAA as Moderate nonattainment for the 2015 ozone NAAQS.[7] The EPA's classification of these areas as Moderate ozone nonattainment established a requirement that each area attain the 2015 ozone NAAQS as expeditiously as practicable, but no later than six years from the date of designation as nonattainment, *i.e.,* August 3, 2024.[8]

In August 2020, CARB submitted to the EPA a request from the air districts in the Sacramento Metro area[9] to voluntarily reclassify the Sacramento Metro ozone nonattainment area from Moderate to Serious nonattainment for the 2015 ozone NAAQS.[10] In May 2021, CARB submitted to the EPA requests from the Eastern Kern Air Pollution Control District and the Northern Sierra Air Quality Management District to voluntarily reclassify the Eastern Kern and Western Nevada ozone nonattainment areas, respectively, from Moderate to Serious nonattainment for the 2015 ozone NAAQS.[11] In this document, we refer to the air districts in the Sacramento Metro, Eastern Kern, and Western Nevada nonattainment areas collectively as the ''districts.'' Under the EPA's ozone implementation rules at 40 CFR 51.1303(b), the EPA must approve a state's request, for any reason, for a higher classification for an ozone nonattainment area, in accordance with CAA section 181(b)(3).[12] We find that the plain language of CAA section 181(b)(3) and 40 CFR 51.1303(b) mandates that we approve these voluntary reclassification requests, and thus, the EPA proposes in this action to grant CARB's request to reclassify the Eastern Kern, Sacramento Metro, and Western Nevada nonattainment areas from Moderate to Serious for the 2015 ozone NAAQS.

II. Serious Area Requirements and Proposed Schedule

In this action, we are proposing to reclassify the Eastern Kern, Sacramento Metro, and Western Nevada nonattainment areas from Moderate to Serious for the 2015 ozone NAAQS. We are also proposing to establish a schedule for the State to submit SIP revisions to address the planning requirements made applicable to each area as a result of its higher classification, including both the general air quality planning requirements under CAA section 172(c) and the specific requirements for Serious areas under CAA section 182(c), as interpreted and described in the final SIP Requirements Rule for the 2015 ozone NAAQS (''2015 Ozone SRR'').[13] Deadlines for the submittal of specific planning elements are described in Section II of this notice. Upon the effective date of a final action granting the reclassification, the areas would be required to attain the 2015 ozone NAAQS as expeditiously as practicable, but no later than nine years from the effective date of designation as nonattainment, *i.e.,* no later than August 3, 2027.

A. Serious Area Plan Requirements in General

The 2015 Ozone SRR requires states to submit a SIP revision including a Serious area attainment demonstration, reasonable further progress demonstration, reasonably available control measures, and contingency measures for the 2015 ozone NAAQS no later than four years from the area's date of designation as nonattainment.[14] Additionally, for the Sacramento area, California would be required to certify that its current motor vehicle inspection and maintenance (I/M) program meets the requirements for an enhanced I/M program as required by the CAA and the EPA's I/M regulations.[15] CARB would also need to either submit a SIP revision that addresses the CAA's requirements for a clean fuel vehicle program or certify that that its currently approved substitute measure continues to meet CAA requirements.[16] Neither Eastern Kern nor Western Nevada meet the minimum population-based applicability thresholds for the enhanced I/M and clean fuel vehicle program requirements.[17] We are proposing not to alter the four-year schedule for submittal of Serious area SIP revisions under the 2015 Ozone SRR. Therefore, following the EPA's final reclassification of Eastern Kern, Sacramento Metro, and Western Nevada to Serious ozone nonattainment, CARB would be required to submit a SIP revision addressing the Serious area elements listed in this section by August 3, 2022 (*i.e.,* four years from the areas' designation as nonattainment).

B. New Source Review and Title V Program Revisions

Typically, when we reclassify an area to a higher ozone classification, the state must amend its new source review (NSR) rules for the area to reflect the lower NSR major source threshold, lower major modification threshold (as applicable), and higher NSR offset ratio corresponding to the higher classification. Under CAA 182(c), the major source threshold for areas reclassified from Moderate to Serious is lowered from 100 tons per year (tpy) to 50 tpy. Under the EPA's NSR regulations, the significant emissions rates that define major modifications for NO_X and VOC in areas reclassified from Moderate to Serious are lowered from 40 tpy to 25 tpy.[18] Under CAA section 182(c)(10), the VOC and NO_X offset ratios for major sources and modifications in a Serious nonattainment area must be at least 1.2 to 1. Reclassification to Serious ozone nonattainment would typically also

[4] Kern County is located in the southernmost portion of California's Central Valley. The Eastern Kern ozone nonattainment area, which lies within the Mojave Desert air basin, covers the eastern portion of Kern County, excluding Indian Wells Valley. The western portion of Kern County lies within the San Joaquin Valley air basin and is included within the San Joaquin Valley ozone nonattainment area. For more detail on the boundaries of the Eastern Kern ozone nonattainment area, see the entry for ''Kern County (Eastern Kern), CA'' in the 2015 ozone table in 40 CFR 81.305.

[5] The Sacramento Metro nonattainment area includes Sacramento and Yolo Counties, the eastern portion of Solano County, the western portions of Placer and El Dorado counties outside of the Lake Tahoe Basin, and the southern portion of Sutter County. For more detail on the boundaries of the Sacramento Metro ozone nonattainment area, see the entry for ''Sacramento Metro, CA'' in the 2015 ozone table in 40 CFR 81.305.

[6] Nevada County is located in the north-central Sierra Nevada Range and includes portions of Tahoe National Forest. The easternmost portion of Nevada County is excluded from the Western Nevada ozone nonattainment area and is designated unclassified or attainment for the 2015 ozone NAAQS. For more detail on the boundaries of the Western Nevada ozone nonattainment area, see the entry for ''Nevada County (Western part), CA'' in the 2015 ozone table in 40 CFR 81.305.

[7] 83 FR 25776 (June 4, 2018).

[8] See 40 CFR 51.1303(a).

[9] The Sacramento Metro area is regulated by five local air districts: The Sacramento Metropolitan Air Quality Management District (AQMD), the Feather River AQMD, the El Dorado County AQMD, the Yolo-Solano AQMD, and the Placer County Air Pollution Control District.

[10] Letter dated August 3, 2020, from Richard W. Corey, Executive Officer, CARB, to John Busterud, Regional Administrator, EPA Region IX, requesting voluntary reclassification of Sacramento Metro to Serious nonattainment for the 2015 ozone NAAQS.

[11] Letters, dated April 30, 2021 and May 15, 2021, from Richard W. Corey, Executive Officer, CARB, to Deborah Jordan, Acting Regional Administrator, EPA Region IX, requesting voluntary reclassification of Western Nevada and Eastern Kern to Serious nonattainment for the 2015 ozone NAAQS, respectively.

[12] CAA section 181(b)(3) provides that the EPA shall grant the request of any state to reclassify an ozone nonattainment area to a higher classification.

[13] The EPA promulgated the 2015 Ozone SRR at 40 CFR part 51, subpart CC.

[14] See CAA section 182(c) and 83 FR 62988. We encourage CARB and the districts to work with EPA Region IX staff to confirm the specific planning requirements applicable to each area.

[15] CAA section 182(c)(3) and 40 CFR part 51 subpart S.

[16] CAA sections 182(c)(4) and 246(a).

[17] CAA section 182(c)(3)(A) and 246(a), respectively.

[18] 40 CFR 51.165(a)(1)(x).

require changes to the districts' title V operating permits programs necessary to reflect the change in the major source threshold for Serious areas.

The Eastern Kern and Western Nevada ozone nonattainment areas are currently classified as Serious for the 2008 ozone NAAQS and therefore are currently subject to the lower major source and major modification thresholds and higher offset ratios applicable to Serious ozone nonattainment areas. The Sacramento Metro nonattainment area is classified as Severe for the 2008 ozone NAAQS and is therefore subject to the more stringent major source and major modification thresholds and offset ratio applicable to Severe ozone nonattainment areas. For this reason, we anticipate that reclassification to Serious for the 2015 ozone NAAQS will not require the districts to amend their NSR rules to incorporate the requirements for Serious nonattainment areas and that the districts may therefore satisfy the applicable NSR requirements by certifying that their current NSR programs address Serious area requirements.

We are proposing under our general CAA section 301(a) authority to establish a deadline of August 3, 2022, for the State to submit, for each area, revised NSR rules or a certification that the area's current NSR program is sufficient to meet the applicable requirements. We are also proposing under CAA section 301(a) to establish a deadline of August 3, 2022, for each area to submit revised title V program rules reflecting the Serious area major source definition. Given the narrow scope of the required revisions, we anticipate a deadline of August 3, 2022, will allow the districts sufficient time to make the required changes without imposing a lengthy delay in the requirement for sources newly subject to the title V program to submit a timely application.[19] Additionally, this date is the same as the submittal due date for other Serious area elements and will allow the districts to submit any NSR and title V revisions together with these other elements.

C. Reasonably Available Control Technology

Ozone nonattainment areas classified as Moderate and above are required to implement reasonably available control technology (RACT) for major sources.[20] Major sources are defined for Moderate areas as sources that emit or have the potential to emit 100 tpy of VOC or NO_X.[21] For Serious areas reclassified from Moderate, the requirement for RACT expands to include all sources that emit, or have the potential to emit, 50 tpy of VOC or NO_X.[22] Thus, following reclassification from Moderate to Serious, states must revise their RACT SIPs to include those other sources emitting or having the potential to emit between 50 and 100 tpy. Under 40 CFR 51.1312(a)(2)(ii), RACT SIP submittals are due 24 months from the effective date of reclassification or a deadline otherwise established by the EPA in the reclassification action. Under 40 CFR 51.1312(a)(3)(ii), RACT requirements triggered by reclassification should be implemented as expeditiously as practicable, but no later than the start of the attainment year ozone season associated with the area's new attainment deadline, or January 1 of the third year after the associated SIP revision submittal deadline, whichever is earlier; or by a deadline otherwise established by the EPA.

Consistent with 40 CFR 51.1312(a)(2)(ii), we are proposing to establish a deadline of 24 months from the effective date of reclassification to Serious for Eastern Kern, Sacramento Metro, and Western Nevada to submit a Serious area RACT SIP. Consistent with 40 CFR 51.1312(a)(3)(ii), we are proposing a deadline for implementation of Serious area RACT rules as expeditiously as practicable but no later than the start of the attainment year ozone season associated with the affected areas' new attainment date (*i.e.,* January 1, 2027, as proposed) [23] or January 1 of the third year after the affected areas' Serious area RACT SIP submittal deadline,[24] whichever is earlier. Eastern Kern, Sacramento Metro, and Western Nevada each remain subject to the Moderate area RACT implementation deadline of January 1, 2023, under 40 CFR 51.1312(a)(3)(i).

D. Transportation Control

CAA section 182(c)(5) requires ozone nonattainment areas that are classified as Serious to submit a demonstration as to whether current aggregate vehicle mileage, aggregate vehicle emissions, congestion levels, and other relevant parameters are consistent with those used for the area's demonstration of attainment. The CAA requires the first report to be submitted 6 years after November 15, 1990, which is two years after the deadline for Serious area attainment demonstrations, and every three years thereafter.[25] Consistent with this schedule, we are proposing that the first report be submitted 24 months after the attainment demonstrations for these areas are due (*i.e.,* August 3, 2024) and every three years thereafter. If a demonstration shows that such parameters and emissions levels exceed the levels projected for purposes of the area's attainment demonstration, the State would be required to develop and submit a SIP revision within 18 months that includes transportation control measures to reduce emissions to levels that are consistent with those projected in the demonstration.[26]

III. Reclassification of Areas of Indian Country

Because the State of California does not have jurisdiction over Indian country geographically located within the borders of the state, CARB's reclassification requests do not apply to the areas of Indian country within the boundaries of the nonattainment areas identified in 40 CFR 81.305. In these areas of Indian country, the EPA implements federal CAA programs, including reclassifications, consistent with our discretionary authority under sections 301(a) and 301(d)(4) of the CAA. There are no tribal lands located within the boundaries of the Eastern Kern and Western Nevada ozone nonattainment areas. The Sacramento Metro ozone nonattainment area includes lands of four federally recognized tribes: The Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract); the United Auburn Indian Community of the Auburn Rancheria of California; the Wilton Rancheria; and the Yocha Dehe Wintun Nation.

The EPA contacted tribal officials from each of the federally recognized tribes having jurisdiction over lands within the boundaries of the Sacramento Metro ozone nonattainment area to invite government-to-government consultation on this rulemaking. Under the EPA's Consultation Policy, the EPA consults on a government-to-government basis with federally recognized tribal governments when the EPA's actions and decisions may affect tribal interests.

[19] A source newly subject to the title V permit program is required to submit a title V application within 12 months after the source becomes subject to the program. See 40 CFR 70.5(a)(1)(i).

[20] CAA sections 182(b)(2) and 182(f).

[21] CAA section 302(j).

[22] CAA sections 182(c) and 182(f).

[23] Because ozone nonattainment areas in California have a year-round ozone season, the start of the attainment year ozone season associated with each area's new attainment date would be January 1, 2027.

[24] If the EPA issues a final reclassification action that is effective in calendar year 2021, January 1 of the third year after the RACT SIP submittal deadline would be January 1, 2026.

[25] CAA section 182(c)(2).

[26] CAA section 182(c)(5).

No tribes requested government-to-government consultation on this action.

We have considered the relevance of our proposal to reclassify the Sacramento Metro area as Serious nonattainment for the 2015 ozone NAAQS for each tribe located within the Sacramento Metro area. We believe that the same facts and circumstances that support the proposal for the non-Indian country lands also support the proposal for reservation areas of Indian country and any other areas of Indian country where the EPA or a tribe has demonstrated that the tribe has jurisdiction located within the Sacramento Metro area. In this particular case, the State's reclassification request is based on modeling results that show that a longer timeframe is necessary to attain the 2015 ozone NAAQS for the Sacramento Metro area. The longer timeframes will provide the time necessary to realize full implementation of the stationary and mobile source regulations contained in the districts' attainment plans. Additionally, uniformity of classification throughout a nonattainment area is a guiding principle and premise when an area is being reclassified. Ozone and ozone precursors are pervasive pollutants that can be transported throughout a nonattainment area. Therefore, boundaries for nonattainment areas are drawn to encompass both areas with direct sources of pollution as well as nearby areas in the same airshed in which ozone can be transported. Each nonattainment area is assigned an initial classification that applies consistently within the boundaries of the area. The EPA believes this approach best ensures public health protection from the adverse effects of ozone pollution. Therefore, it is generally counterproductive from an air quality and planning perspective to have a different classification for a land area located within the boundaries of a nonattainment area, such as the areas of Indian country in the Sacramento Metro ozone nonattainment area. Accordingly, based on the EPA's discretionary authority under sections 301(a) and 301(d)(4) of the CAA to implement federal CAA programs in these areas of Indian country, including reclassifications, the EPA is proposing to reclassify areas of Indian country geographically located in the Sacramento Metro area to Serious nonattainment for the 2015 ozone NAAQS.

The Sacramento Metro area and the tribes located within its boundaries are currently designated as Severe, *i.e.,* one classification higher than Serious, for the 1997 and 2008 ozone NAAQS. An area's applicable major source thresholds and offset ratios for NSR and title V programs are based on the area's highest ozone classification. Because these areas of Indian country are already classified as a higher classification for the 1997 and 2008 ozone NAAQS, the major source thresholds and offset ratios for NSR and title V programs applicable to the tribes in the Sacramento Metro area will not change. This reclassification also will not affect projects proposed in these areas of Indian country that require federal permits, approvals, or funding under the EPA's general conformity rule because such projects are already subject to the de minimis thresholds and offset ratios for Severe ozone nonattainment areas. We note that, while eligible tribes may seek EPA approval of relevant tribal programs under the CAA, none of the affected tribes would be required to submit an implementation plan as a result of this reclassification.

In light of the considerations outlined in this notice that support retention of a uniformly-classified ozone nonattainment area and our proposal to approve the State's voluntary reclassification request, we propose to reclassify the entire Sacramento Metro nonattainment area, including reservation areas of Indian country and any other area of Indian country located within it where the EPA or a tribe has demonstrated that the tribe has jurisdiction, as Serious nonattainment for the 2015 ozone NAAQS. The EPA specifically solicits additional comment on this proposed rule from tribal officials.

IV. Proposed Action and Request for Public Comment

Pursuant to CAA section 181(b)(3), we are proposing to grant CARB's request to reclassify the Eastern Kern, Sacramento Metro, and Western Nevada ozone nonattainment areas from Moderate to Serious for the 2015 ozone NAAQS. As described in Section III of this notice, our proposal to reclassify Sacramento Metro to Serious for the 2015 ozone NAAQS includes reservation areas of Indian country and any other area of Indian country located within it where the EPA or a tribe has demonstrated that the tribe has jurisdiction.

As described in Section II of this document, the EPA is proposing a schedule for the State and districts to submit SIP revisions addressing Serious area requirements and to submit revisions to the title V operating permit rules for Eastern Kern, Sacramento Metro, and Western Nevada. Under the EPA's proposed schedule, California would be required to submit SIP revisions addressing Serious area requirements for the affected areas, including an attainment demonstration, reasonable further progress demonstration, reasonably available control measures, contingency measures, motor vehicle I/M program, and clean fuel vehicle program, as applicable, by August 3, 2022. Submittal of any corresponding revisions to NSR and title V program rules that apply in the affected areas would also be due by August 3, 2022. A SIP revision including Serious area RACT rules for the affected areas would be due 24 months from the effective date of the reclassification. Lastly, the EPA is proposing a deadline for implementation of Serious area RACT rules as expeditiously as practicable but no later than the start of the attainment year ozone season associated with the affected areas' new attainment date or January 1 of the third year after the affected areas' Serious area RACT SIP submittal deadline, whichever is earlier. We will accept comments from the public on this proposed rule for the next 30 days. The deadline and instructions for submission of comments are provided in the **DATES** and **ADDRESSES** sections at the beginning of this preamble.

V. Statutory and Executive Order Reviews

Under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011), this proposed action is not a ''significant regulatory action'' and therefore is not subject to Executive Order 12866. With respect to lands under state jurisdiction, voluntary reclassifications under CAA section 181(b)(3) are based solely upon requests by the state, and the EPA is required under the CAA to grant them. These actions do not, in and of themselves, impose any new requirements on any sectors of the economy. In addition, because the statutory requirements are clearly defined with respect to the differently classified areas, and because those requirements are automatically triggered by reclassification, reclassification does not impose a materially adverse impact under Executive Order 12866. For these reasons, this proposed action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

In addition, I certify that this proposed rule will not have a significant economic impact on a substantial number of small entities under the

Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and that this proposed rule does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), because the EPA is required to grant requests by states for voluntary reclassifications, and such reclassifications in and of themselves do not impose any federal intergovernmental mandate, and because tribes are not subject to implementation plan submittal deadlines that apply to states as a result of reclassifications.

Executive Order 13175 (65 FR 67249, November 9, 2000) requires the EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in Executive Order 13175 to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.'' Four Indian tribes have areas of Indian country located within the boundaries of the Sacramento Metro ozone nonattainment area, and there are no areas of Indian country located in the Eastern Kern and Western Nevada ozone nonattainment areas. The EPA implements federal CAA programs, including reclassifications, in these areas of Indian country within the boundaries of the Sacramento Metro area, consistent with our discretionary authority under sections 301(a) and 301(d)(4) of the CAA. The EPA has concluded that this proposed rule might have tribal implications for the purposes of Executive Order 13175 but would not impose substantial direct costs upon the tribes, nor would it preempt Tribal law. As discussed in Section III of this document, this proposed rule does not affect the implementation of NSR or title V programs in these areas of Indian country, nor does it affect projects proposed in these areas of Indian country that require federal permits, approvals, or funding under the EPA's general conformity rule. None of the affected tribes would be required to submit an implementation plan as a result of this reclassification.

The EPA contacted tribal officials early in the process of developing this proposed rule to provide an opportunity to have meaningful and timely input into its development. On December 11, 2020, we sent letters to leaders of the four tribal governments representing the areas of Indian country in the nonattainment area offering government-to-government consultation and seeking input on how we could best communicate with the tribes on this rulemaking effort. No tribes requested government-to-government consultation on this action.

Executive Order 12898 establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. This reclassification action does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898.

This proposed action also does not have federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, nor on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This proposed action does not alter the relationship or the distribution of power and responsibilities established in the CAA.

This proposed rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because the EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation.

As this proposal would set a deadline for the submittal of CAA required plans and information, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, National parks, Ozone, Wilderness areas.

Dated: July 13, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2021–16446 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[GN Docket No. 13–111; FCC 21–82; FR ID 39501]

Promoting Technological Solutions To Combat Contraband Wireless Device Use in Correctional Facilities

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) takes further steps to facilitate the deployment and viability of technological solutions used to combat contraband wireless devices in correctional facilities. The *Second Further Notice of Proposed Rulemaking (SFNPRM)* seeks further comment on the relative effectiveness, viability, and cost of additional technological solutions to combat contraband phone use in correctional facilities previously identified in the record.

DATES: Interested parties may file comments on or before September 13, 2021, and reply comments on or before October 12, 2021.

ADDRESSES: You may submit comments, identified by GN Docket No. 13–111, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the Commission's Electronic Comment Filing System (ECFS): *http://apps.fcc.gov/ecfs/*.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.
- Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

• U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.

• Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy, Public Notice, DA 20–304 (March 19, 2020). *https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy*.

People with Disabilities: To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

FOR FURTHER INFORMATION CONTACT: Melissa Conway of the Wireless Telecommunications Bureau, Mobility Division, at (202) 418–2887 or *Melissa.Conway@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Second Further Notice of Proposed Rulemaking* in GN Docket No. 13–111, FCC 21–82 adopted July 12, 2021 and released July 13, 2020. The full text of this document, including all Appendices, is available for inspection and copying during normal business hours in the FCC Reference Center, 45 L Street NE, Washington, DC 20554, or available for viewing via the Commission's ECFS website by entering the docket number, GN Docket No. 13–111. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *FCC504@fcc.gov* or calling the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

This proceeding shall continue to be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules (47 CFR 1.1200 through 1.1216). Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule § 1.1206(b). In proceedings governed by rule § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Synopsis

1. In the *SFNPRM,* the Commission seeks comment on whether there have been technological, economic, policy, and/or legal developments sufficient to overcome the variety of challenges presented to the widespread deployment of these technologies and whether and how the Commission can further facilitate these technologies through regulatory next steps. In doing so, the Commission contemplates various approaches to combatting the use of contraband wireless devices in correctional facilities that would each have their own projected reporting, recordkeeping, and other compliance requirements. We cannot quantify the cost of compliance with any regulatory next steps and do not know whether small entities will have to hire professionals to comply with any rules that we ultimately adopt. Below we discuss the projected reporting, recordkeeping, and other compliance requirements associated with the various approaches in the *SFNPRM* to combat contraband wireless device use in correctional facilities.

2. The Commission contemplates as a potential solution the creation of ''quiet zones'' in and around correctional facilities where wireless communications are not authorized such that contraband wireless devices in correctional facilities would not be able to receive service from a wireless provider. Quiet zones would require wireless carriers and solution providers to have appropriate engineering capabilities to precisely define quiet zones around the borders of correctional facilities. To understand the cost implications for small and other entities, we seek comment on the potential costs that could be associated with the implementation of quiet zones, including the cost of hardware, software, network integration, engineering, and ongoing maintenance. The Commission also seeks comment on who should bear the cost of implementing quiet zones, and the potential alternatives to a Commission mandate that might encourage implementation.

3. The *SFNPRM* seeks comments on the options of geolocation-based denial, also known as geofencing, and a ''network-based solution.'' The geolocation-based denial would allow for mobile device software and/or hardware to be used to shut down contraband wireless devices that violate a perimeter surrounding a correctional facility. A geolocation-based solution would require adequate engineering to locate and disable wireless contraband. Relatedly, a ''network-based solution'' would require commercial mobile radio service (CMRS) licensees to independently identify and disable contraband wireless devices in correctional facilities using their own network elements. Therefore, the Commission seeks comment on whether there have been technological advancements in carriers' network engineering that might make it more feasible for entities to implement and comply with network-based geofencing. If network-based geofencing is selected as the solution for contraband wireless devices in correctional facilities, then the engineering required could have associated costs, including the testing and maintenance necessary to ensure accuracy and ongoing viability. The Commission's request for comment on additional costs that could be associated with the implementation of network-based geofencing, including software and network integration, should provide insight and allow us to evaluate costs for small and other entities that will be impacted by any future rules we adopt regarding these two potential solutions.

4. This *SFNPRM* also contemplates the option of using beacon technology to combat the issue of contraband wireless device use in correctional facilities. The

Commission seeks comment on the potential advancements in beacon technology that would allow beacon software to be installed on mobile devices remotely (*e.g.,* through a software update). If the Commission is found to have the authority to require entities to install the software on devices, then this approach could require related compliance requirements. Relatedly, the Commission seeks comment on how beacon technology could ensure that authorized users (*e.g.,* correctional officers) are still able to use their devices. This requirement could impose recordkeeping and compliance requirements for entities such as wireless providers and mobile device manufacturers that must implement beacon technology via hardware and/or software changes to mobile devices for all users. We raise inquiries and seek information on the cost and implementation timing for beacon technology, specifically as compared to managed access systems (MAS) or advanced detection, and who should bear these costs. In addition, we request information on the various types of costs for entities associated with this type of technology, including hardware, software, network integration, engineering, ongoing maintenance, etc., which is germane to our analysis of any regulatory next steps and could impact the nature and type of recordkeeping, reporting, and compliance obligations that may result in this proceeding.

5. The Commission also seeks further comment on potential regulatory steps that might be necessary to ensure that MAS maintains effectiveness as wireless technology evolves from 2G to widespread 3G/4G and ultimately 5G deployments. We note that the commenters on the *July 2020 Refresh Public Notification* (85 FR 49999, August 17, 2020) largely agree that MAS Evolved will be even more effective than existing MAS systems. In this *SFNPRM,* we seek further comment on steps the Commission could take to facilitate MAS deployments. Depending on the comments, it is possible that the Commission could mandate roaming agreements between wireless carriers and solutions providers in the corrections context given the vital public safety concerns, which would impact small entities. It is also possible that the Commission could implement other approaches that could be developed by the wireless providers and/or the vendors to add features or services and help defray the cost of MAS deployments and operations. Lastly, the Commission could revise the previously streamlined leasing rules in the correctional facility context to facilitate further Contraband Interdiction System (CIS) deployments nationwide. Each of these potential rule changes could require additional recordkeeping and reporting from entities that seek to deploy MAS Evolved solutions.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2021–16463 Filed 8–12–21; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 86, No. 154
Friday, August 13, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Information Collection; Safeguarding Against Exploitation, Sexual Abuse, Child Abuse, and Neglect

AGENCY: U.S. Agency for International Development.

ACTION: Notice and request for comments.

SUMMARY: U.S. Agency for International Development (USAID), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995. Comments are requested concerning whether the proposed collection of information is necessary for sustaining USAID-funded programming; the accuracy of USAID's estimate of the burden of the proposed collection of information; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents. This notice provides 60 days for public comment preceding submission of the collection to OMB.

DATES: Comments must be received no later than October 12, 2021.

ADDRESSES: USAID invites interested persons to submit comments on this collection through the following methods:

1. *Web:* Through the Federal eRulemaking Portal at *http://www.regulations.gov.* This website provides instructions and includes the ability to type short comments directly into the comment field or attach a file for lengthier comments.

2. *Email:* For comments sent via email, please address them to *aapsm@usaid.gov* and cite OMB Control Number XXXX–XXXX Safeguarding Against Exploitation, Sexual Abuse, Child Abuse, and Neglect in the subject line of the email. Email submissions must be received before the close of the comment period.

FOR FURTHER INFORMATION CONTACT: Keetah Salazar-Thompson via email to *aapsm@usaid.gov.*

Instructions: Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

SUPPLEMENTARY INFORMATION:

A. Need and Uses

The purpose of this collection is to enable the U.S. Agency for International Development to respond to allegations of exploitation, sexual abuse, child abuse, and neglect and institute appropriate standards of behavior. Submissions will be required from Recipients to comply with pending award requirements to safeguard against exploitation, sexual abuse, child abuse, and neglect in USAID-funded programming. Information submitted by Recipients as part of this collection will be presumed to be confidential. USAID takes the protection of personally identifiable information (PII) seriously and takes precautions to ensure the confidentiality and security of PII, consistent with USAID's *Automated Directives System (ADS) Chapter 508.*

Notification. A pending standard provision for assistance awards will require Recipients to immediately notify, in writing, the Agreement Officer and the USAID Office of the Inspector General of—

(1) Any credible information it receives from any source (including host country law enforcement) that alleges the Recipient or subrecipient, or personnel, invitee, or agent of the Recipient or a subrecipient has engaged in or tolerated exploitation, sexual abuse, child abuse, or neglect.

(2) Any actions planned or taken against a subrecipient, personnel, invitee, or agent of the Recipient or a subrecipient pursuant to this provision.

(3) Any actions planned or taken by the Recipient or subrecipient to assess, address, or mitigate factors that contributed to the incident occurring.

Compliance Plan. If the estimated value of services required to be performed under the award outside the United States exceeds $500,000, the Recipients will maintain a ''Safeguarding Against Exploitation, Sexual Abuse, Child Abuse, and Neglect Compliance Plan,'' either in conjunction with or separate from the Trafficking in Persons Compliance Plan, that details risk analysis and mitigation measures that will be implemented during the course of the award to prevent and address exploitation, sexual abuse, child abuse, and neglect, consistent with the minimum set of policies and internal controls necessary to prevent, detect, address, and respond to allegations of exploitation, sexual abuse, child abuse, and neglect, and take appropriate action against, personnel, invitees, subrecipients, and agents that commit exploitation, sexual abuse, child abuse, or neglect or those who fail to take reasonable steps to prevent it. The Recipient's compliance plan must be appropriate to the size and complexity of the award and to the nature and scope of the activities, including the particular risks presented by the operating context and the assistance, services or supplies provided. Recipients will be required to provide the compliance plan to the Agreement Officer upon request. The plan must include, at a minimum, the following:

(a) An awareness program to inform its personnel, invitees, or agents about USAID's zero tolerance policy for inaction regarding exploitation, sexual abuse, child abuse, and neglect and the minimum set of policies and internal controls necessary to prevent, detect, address, and resolve allegations of exploitation, sexual abuse, child abuse, and neglect, and take appropriate action against subrecipients, personnel, invitees, and agents that commit exploitation, sexual abuse, child abuse, or neglect or those who fail to take reasonable steps to prevent it, including the activities prohibited and the action that will be taken in response to violations;

(b) A description of how project beneficiaries are made aware that engaging in or tolerating exploitation, sexual abuse, child abuse, and neglect is prohibited, the Recipient's survivor-centered approach for response, and how beneficiaries can report allegations of exploitation, sexual abuse, child abuse, and neglect;

(c) Accessible reporting processes for anyone to report, without fear of retaliation, exploitation, sexual abuse, child abuse, and neglect; and

(d) Procedures for the Recipient to prevent any of its personnel, invitees, or agents or subrecipient at any tier and at any dollar value from engaging in or tolerating exploitation, sexual abuse, child abuse, and neglect. The Recipient must also have procedures to monitor, detect, and terminate, or take any other actions as may be appropriate, for any of its personnel, invitees, or agents, subrecipients or subrecipient personnel that have engaged in such activities.

B. Annual Burden

There will be a small, but measurable reporting burden for the notification of any credible information of exploitation, sexual abuse, child abuse, or neglect and any actions taken in response by any Recipient. Information in the notifications should include: The award title and number, the location of the program, name of the organization, a point of contact, the type of allegation, and the position(s) of those involved, and if beneficiaries or minors were involved. The notification may also identify any actions taken to investigate or respond to the allegation, including referral to local authorities. If known or available, next steps to address the perpetrator and/or the survivor's and whistleblower's safety, resources and information available to the survivor, and any established organizational procedures or framework to respond may also be provided. The notifications should include: Any interim or final measures taken or planned to ensure accountability of the alleged perpetrator, as well as protective measures or reforms, such as changes to applicable policies and procedures, in order to assess, address, or mitigate factors that contributed to the incident. USAID expects reporting to increase as awareness for this requirement increases in the short-term. Therefore, the annual reporting burden for notification to USAID is estimated as follows:

Respondents: 253.

Responses per respondent: 2.

Preparation hours per response: 4 hours.

Total response burden hours: 2,024.

Public reporting and recordkeeping burden for this collection of information is estimated to average 24 hours to prepare a compliance plan, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The number below includes all grants and estimated subawards over $500,000 required to be performed outside the United States.

The annual recordkeeping burden for the compliance plan is estimated as follows:

Recordkeepers: 2,365.

Records per recordkeeper: 1.

Preparation hours per response: 24.

Total recordkeeping burden hours: 56,760.

For Recipients that meet the $500,000 threshold to maintain a compliance plan, there will be a small but measurable reporting burden for submission of that compliance plan, but only when it is requested by the Agreement Officer. We anticipate that requests to submit the compliance plan will only occur in circumstances where the Agreement Officer has reason to believe that there may be exploitation, sexual abuse, child abuse, or neglect in USAID funded programming. Therefore, the annual reporting burden for submission of the compliance plan to USAID is estimated as follows:

Respondents: 200.

Responses per respondent: 1.

Preparation hours per response: 1.

Total response burden hours: 200.

Keetah Salazar-Thompson,

Coordinator, Action Alliance for Preventing Sexual Misconduct, U.S. Agency for International Development.

[FR Doc. 2021–17340 Filed 8–12–21; 8:45 am]

BILLING CODE 6116–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection: Forest Industries and Logging Operations Data Collection Systems

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension with revision of a currently approved information collection, Forest Industries and Logging Operations Data Collection Systems.

DATES: Comments must be received in writing on or before October 12, 2021 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to:

Email: consuelo.brandeis@usda.gov.

Mail: Consuelo Brandeis, Southern Research Station, Forest Inventory and Analysis, Department of Agriculture, Forest Service, 4700 Old Kingston Pike, Knoxville, TN 37919.

Telephone: 865–862–2028.

Facsimile: 865–862–0262.

Comments submitted in response to this notice may be made available to the public through relevant websites and upon request. For this reason, please do not include any information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Consuelo Brandeis, Southern Research Station, at 865–862–2028. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Forest Industries and Logging Operations Data Collection Systems.

OMB Number: 0596–0010.

Expiration Date of Approval: February 28, 2022.

Type of Request: Extension with revision of a currently approved information collection.

Abstract: The Forest and Range Renewable Resources Planning Act of 1974 and the Forest and Rangeland Renewable Resources Research Act of 1978 require the Forest Service to evaluate trends in the use of roundwood (logs in whole or chipped form), to forecast anticipated levels of roundwood use and availability, and to analyze changes in the harvest of these resources from the United States' forests. This data collection effort has been conducted since the mid-1970s, with various adjustments through time to accommodate new questions, sampling approaches, and/or data collection needs. Data collection is performed by Forest Service personnel and cooperators from State natural resource agencies and universities. Currently, the data collection gathers information from two groups: Primary wood industry and logging operations.

Primary Wood Industry Questionnaire: This questionnaire is used by the Forest Service to collect and evaluate information from primary wood-using mills, including small, part-time mills, as well as large corporate

entities. Primary wood-using mills are facilities that use roundwood to manufacture a primary product, such as lumber, wood pulp, veneer, etc. Forest Service personnel evaluate the information collected and use it to monitor volume of roundwood harvested throughout the Nation by primary product type, tree species, and origin. The information gathered is not available from other sources and provides baseline data for resource analyses, which are a key component in the formulation of forestry programs, industrial expansion decisions, and forest policy. Primary wood industry questionnaires are delivered to mills via regular mail or through email. Responses are collected through email, regular mail, phone interviews, or personal mill visits.

Logging Operations Questionnaire: This questionnaire is used by the Forest Service to collect and evaluate information from logging operations to help characterize the logging industry and its response to outside influences. The information is used to measure the 'health' of the logging industry as well as to provide background information for decision-making. The logging operations questionnaire is administered in person by field personnel during tree utilization data collection at sampled logging sites.

For this extension, we are proposing to revise the questionnaire for the primary wood industry survey to simplify the format and eliminate questions that are no longer needed. At the same time, we propose to test a few survey mechanisms that could help improve survey response and lower respondents' burden by piloting various survey structures including different questionnaire lengths (*e.g.,* a three-question post-card or a short version of the traditional survey). We also propose using a cognitive survey to assess respondent's understanding of the survey questions and to identify areas of potential clarification. These proposed tests are in direct response to comments from data users, state partners, and other stakeholders indicating the need to adopt new approaches to motivate higher response rates. The logging operations survey will remain unchanged from the currently approved version.

In summary, this information collection will generate scientifically based, statistically reliable, up-to-date information about utilization of timber resources of the United States. Our testing efforts will allow us to improve the quality of data obtained. The results of these efforts contribute to the availability of reliable information on timber resource use, facilitating more complete and accurate assessments of forest resources at state, regional, and national levels.

Affected Public: Individuals and the Private Sector (Businesses). In particular, mill owners and representatives, procurement foresters and loggers.

Estimate of Burden per Response: Accounting for the proposed tests, the primary wood industry questionnaire's estimated burdens are 41 minutes for the traditional format, to be delivered to a sample of 2,500 mills; 25 minutes for the short-form test version going to a sample of 98 mills; five minutes for the three-question post-card test to be sent to a sample of 2,500 mills; five minutes to a sample of 500 mills which will be screened for the cognitive interview; and 60 minutes for the cognitive interviews to be conducted for 20 mills identified during the screening process. Estimated time burden for the logging operations questionnaire is 11 minutes to be distributed to a sample of 150 logging operations.

Estimated Annual Number of Respondents: 5,768.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 2,060 hours.

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the information collection, including validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the information collection on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

Alexander L. Friend,

Deputy Chief, Research and Development.

[FR Doc. 2021–17319 Filed 8–12–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Request for Applications: The Community Forest and Open Space Conservation Program

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Request for applications.

SUMMARY: The Forest Service, U.S. Department of Agriculture (USDA), State and Private Forestry, and Cooperative Forestry staff requests applications for the Community Forest and Open Space Conservation Program (Community Forest Program or CFP). This is a competitive grant program whereby local governments, qualified nonprofit organizations, and Indian tribes are eligible to apply for grants to establish community forests through fee simple acquisition of private forest land from a willing seller. The purpose of the program is to establish community forests by protecting forest land from conversion to non-forest uses and provide community benefits such as sustainable forest management; environmental benefits including clean air, water, and wildlife habitat; benefits from forest-based educational programs; benefits from serving as models of effective forest stewardship; and recreational benefits secured with public access.

DATES: Interested local government and nonprofit applicants must submit applications to the State Forester. Tribal applicants must submit applications to the appropriate Tribal government officials. All applications, either hardcopy or electronic, must be received by State Foresters or Tribal governments by January 10th, 2022. State Foresters or Tribal government officials must forward applications to the appropriate Forest Service Regional office or International Institute of Tropical Forestry by February 7th, 2022.

ADDRESSES: All local government and qualified nonprofit organization applications must be submitted to the State Forester of the State where the property is located. All Tribal applications must be submitted to the equivalent Tribal government official. Applicants are encouraged to contact and work with the Forest Service Region or International Institute of Tropical Forestry, and State Forester or equivalent Tribal government official when developing their proposal. Applicants must consult with the State Forester and equivalent Tribal government official prior to requesting technical assistance for a project. The

State Forester's member roster may be found on *https://www.stateforesters.org/who-we-are/our-membership/.* All applicants must also send an email to *SM.FS.CFP@usda.gov* to confirm an application has been submitted for funding consideration.

State Foresters and Tribal government officials shall submit applications, either electronic or hardcopy, to the appropriate Forest Service Region/Institute contact noted below.

Northern and Intermountain Regions

Regions 1 and 4

(ID, MT, ND, NV, UT)

Janet Valle, USDA Forest Service, 324 25th St., Ogden, UT 84401, 801–710–3795 (mobile), *janet.valle@usda.gov*

Rocky Mountain Region

Region 2

(CO, KS, NE, SD, WY)

Claire Harper, USDA Forest Service, 1617 Cole Boulevard, Bldg. 17, Lakewood, CO 80401, 303–895–6157 (mobile), *claire.harper@usda.gov*

Southwestern Region

Region 3

(AZ, NM)

Laura Moser, USDA Forest Service, 333 Broadway SE, Albuquerque, NM 87102, 928–607–6040 (mobile), *laura.moser@usda.gov*

Pacific Southwest Region

Region 5

(CA)

Dana Walsh, USDA Forest Service, 1323 Club Drive, Vallejo, CA 94592, 530–450–5555 (mobile), *dana.walsh@usda.gov*

(Hawaii, Guam, American Samoa, Federated States of Micronesia and other Pacific Islands)

Katie Friday, USDA Forest Service, 60 Nowelo St., Hilo, HI 96720, 808–785–5197 (mobile), *kathleen.friday@usda.gov*

Pacific Northwest, and Alaska Regions

Regions 6 and 10

(AK, OR, WA)

Candice Polisky, USDA Forest Service, 1220 SW Third Ave., Portland, OR 97204, 971–710–2346 (mobile), *candice.polisky@usda.gov*

Southern Region

Region 8

(AL, AR, FL, GA, KY, LA, MS, NC, OK, SC, TN, TX, VA)

Susan Granbery, USDA Forest Service, 1720 Peachtree Rd. NW, Suite 700, Atlanta, GA 30309, 770–883–8925 (mobile), *susan.granbery@usda.gov*

International Institute of Tropical Forestry

(PR, VI)

Magaly Figueroa, USDA Forest Service, Jardin Botanico Sur, 1201 Calle Ceiba, San Juan, PR 00926–1119, 787–309–9565 (mobile), *magaly.figueroa@usda.gov*

Eastern Region

Region 9

(CT, DC, DE, IA, IL, IN, MA, MD, ME, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VT, WI, WV)

Neal Bungard, USDA Forest Service, 271 Mast Road, Durham, NH 03824, 603–833–3287 (mobile), *neal.bungard@usda.gov*

FOR FURTHER INFORMATION CONTACT: For questions regarding the grant application or administrative regulations, contact Scott Stewart, Program Coordinator, 202–465–5038, *scott.stewart@usda.gov* and Nausheen Iqbal, 202–594–7554, *nausheen.iqbal@usda.gov.* Additional information about the Community Forest and Open Space Conservation Program may be obtained at *https://www.fs.usda.gov/managing-land/private-land/community-forest.*

Individuals who use telecommunications devices for the hearing-impaired (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: Eligible lands for grants funded under this program are private forest that are at least five acres in size, suitable to sustain natural vegetation, and at least 75 percent forested. The lands must also be threatened by conversion to non-forest uses, must not be held in trust by the United States on behalf of any Indian Tribe, must not be Tribal allotment lands, must be offered for sale by a willing seller, and if acquired by an eligible entity, must provide defined community benefits under CFP and allow public access.

CFDA number 10.689: To address the goals of Section 7A of the Cooperative Forestry Assistance Act of 1978 (16 U.S.C. 2103d) as amended, the Forest Service is requesting proposals for community forest projects that protect forest land that has been identified as a national, regional, or local priority for protection and to assist communities in acquiring forestland that will provide public recreation, environmental and economic benefits, and forest-based educational programs.

Detailed information regarding what to include in the application, definitions of terms, eligibility, and necessary prerequisites for consideration can be found in the final program rule, published April 2, 2021 (86 FR 17302), which is available at *https://www.fs.usda.gov/managing-land/private-land/community-forest/program.*

Grant Application Requirements

1. Eligibility Information

a. *Eligible Applicants.* A local governmental entity, Indian Tribe (including Alaska Native Corporations), or a qualified nonprofit organization that is qualified to acquire and manage land. Individuals are not eligible to receive funds through this program.

b. *Cost Sharing (Matching Requirement).* All applicants must demonstrate a 50 percent match of the total project cost. The match can include cash, in-kind services, or donations, which shall be from a non-Federal source. For additional information, please see § 230.6 of the final rule.

c. *DUNS Number.* All applicants shall include a Data Universal Numbering System (DUNS) number in their application. For this requirement, the applicant is the entity that meets the eligibility criteria and has the legal authority to apply for and receive the grant. For assistance in obtaining a DUNS number at no cost, call the DUNS number request line 1–866–705–5711 or register on-line at *http://fedgov.dnb.com/webform.*

d. *System for Award Management.* All prospective awardees shall be registered in the System for Award Management prior to award, during performance, and through final payment of any grant resulting from this solicitation. Further information can be found at: *https://www.sam.gov/SAM/.* For assistance, contact the Federal Service Desk 1–866–606–8220.

2. Award Information

Funds have not yet been appropriated for CFP in FY 2022. Individual grant applications may not exceed $600,000, which does not include technical assistance requests. The Federal Government's obligation under this program is contingent upon the availability of appropriated funds.

No legal liability on the part of the Government shall be incurred until funds are committed by the grant officer for this program to the applicant in writing. The initial grant period shall be for two years, and acquisition of lands should occur within that timeframe. Lands acquired prior to the grant award are not eligible for CFP funding. The grant may be reasonably extended by the Forest Service when necessary to accommodate unforeseen circumstances in the land acquisition process. Written annual financial performance reports

and semi–annual project performance reports shall be required and submitted to the appropriate grant officer.

Technical assistance funds, totaling not more than 10 percent of all funds, may be allocated to State Foresters and equivalent officials of the Indian tribe. Technical assistance, if provided, will be awarded at the time of the grant. Applicants shall work with State Foresters and equivalent officials of the Indian Tribe to determine technical assistance needs and include the technical assistance request in the project budget.

As funding allows, applications submitted through this request may be funded in future years, subject to the availability of funds and the continued feasibility and viability of the project.

3. Application Information

Application submission. All local governments and qualified nonprofit organizations' applications must be submitted to the State Forester where the property is located by January 10th, 2022. All Tribal applications must be submitted to the equivalent Tribal officials by January 10th, 2022. Applications may be submitted either electronically or hardcopy to the appropriate official. The State Forester's contact information may be found at: *https://www.stateforesters.org/who-we-are/our-membership/.*

All applicants must also send an email to *SM.FS.CFP@usda.gov* to confirm an application has been submitted to the State Forester or equivalent Tribal official for funding consideration.

All State Foresters and Tribal government officials must forward applications to the Forest Service by February 7th, 2022.

4. Application Requirements

The following section outlines grant application requirements:

a. The application can be no more than eight pages long, plus no more than two maps (eight and half inches by eleven inches in size).

b. Documentation verifying that the applicant is an eligible entity and that the land proposed for acquisition is eligible (see § 230.2 of the final rule).

c. Applications must include the following, regarding the property proposed for acquisition:

(1) A description of the property, including acreage and county location;

(2) A description of current land uses, including improvements;

(3) A description of forest type and vegetative cover;

(4) A map of sufficient scale to show the location of the property in relation to roads and other improvements as well as parks, refuges, green/open space, urban natural areas, or other protected lands in the vicinity;

(5) A description of applicable zoning and other land use regulations affecting the property;

(6) A description of the type of community being served and the extent of community benefits, including to underserved communities (see Project Selection Criteria);

(7) A description of relationship of the property within and its contributions to landscape conservation initiatives, as well as any environmental justice initiatives, if applicable; and

(8) A description of any threats of conversion to non-forest uses, including any encumbrances on the property that prevent conversion to non-forest uses.

d. Information regarding the proposed establishment of a community forest, including:

(1) A description of the benefiting community, including demographics, availability of and access to green spaces and other vulnerabilities including health, economic, environmental and climate impacts faced by the community and a description of the associated benefits;

(2) A description of community involvement, including underrepresented communities, to-date in the planning of the community forest acquisition, and the participation of different community groups anticipated in long-term management;

(3) An identification of persons and organizations that support the project, a description of how they represent the greater population of the community benefiting from the establishment and management of the community forest, their specific role in establishing and managing the community forest; and

e. Information regarding the proposed land acquisition, including:

(1) A proposed project budget not exceeding $600,000 and technical assistance needs as coordinated with the State Forester or equivalent Tribal government official (section § 230.6 of the final program rule);

(2) The status of due diligence, including signed option or purchase and sale agreement, title search, minerals determination, and appraisal;

(3) Description and status of cost share (secure, pending, commitment letter, etc.) (section § 230.6 of the final rule);

(4) The status of negotiations with participating landowner(s) including purchase options, contracts, and other terms and conditions of sale;

(5) The proposed timeline for completing the acquisition and establishing the community forest; and;

(6) Long term management costs and funding source(s).

f. Applications must comply with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards also referred to as the Omni Circular (2 CFR part 200).

In order to assist applicants, a Community Forest Road Map can be found on the CFP website at *https://www.fs.usda.gov/managing-land/private-land/community-forest/program.* The application guidance is located at *https://www.fs.usda.gov/sites/default/files/application-guidance-revised.pdf* and the scoring guidance is at *https://www.fs.usda.gov/sites/default/files/ScoringGuidance-revised.pdf.*

5. Forest Service's Project Selection Criteria

a. Using the criteria described below, to the extent practicable, the Forest Service will give priority to applications that maximize the delivery of community benefits, as defined in the final rule (see section § 230.2 of the final rule); and

b. The Forest Service will evaluate all applications received by the State Foresters or equivalent Tribal government officials and award grants based on the following criteria:

(1) Type and extent of community benefits provided, including to underserved communities. Community benefits are defined in the final program rule as:

(i) Economic benefits, such as timber and non-timber products resulting from sustainable forest management, recreation, and tourism;

(ii) Environmental benefits, including clean air and water, stormwater management, wildlife habitat, and cultural resources.

(iii) Benefits from forest-based experiential learning, including K–12 conservation education programs; vocational education programs in disciplines such as forestry and environmental biology; and environmental education through individual study or voluntary participation in programs offered by organizations such as 4–H, Boy or Girl Scouts, Master Gardeners, etc.;

(iv) Benefits from serving as replicable models of effective forest stewardship for private landowners; and

(v) Recreational benefits such as hiking, hunting, and fishing secured through public access.

(2) Extent and nature of community engagement, including participation by

underserved communities, in the establishment and long-term management of the community forest;

(3) Amount of cost share leveraged;

(4) Extent to which the community forest contributes to any landscape conservation initiatives, as well as any applicable environmental justice initiatives;

(5) Extent of due diligence completed on the project, including cost share committed and status of appraisal;

(6) Likelihood that, unprotected, the property would be converted to non-forest uses; and

(7) Costs to the Federal Government.

6. Grant Requirements

a. Once an application is selected, funding will be obligated to the grant recipient through a grant adhering to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards also referred to as the Omni Circular (2 CFR part 200).

b. Forest Service must approve any amendments to a proposal or request to reallocate funding within a grant proposal. If negotiations on a selected project fail, the applicant cannot substitute an alternative site.

c. The grant recipient must comply with the requirements in section § 230.8 in the final rule before funds will be released.

d. After the project has closed, as a requirement of the grant, grant recipients will be required to provide the Forest Service with a Geographic Information System (GIS) shapefile: A digital, vector-based storage format for storing geometric location and associated attribute information, of CFP project tracts and cost share tracts, if applicable.

e. Any funds not expended within the grant period must be de-obligated and revert to the Forest Service.

f. All media, press, signage, and other documents discussing the creation of the community forest must reference the partnership and financial assistance by the Forest Service through the CFP.

Dated: August 9, 2021.

Jaelith Hall-Riviera,

Acting Deputy Chief, State and Private Forestry.

[FR Doc. 2021–17317 Filed 8–12–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Rural-Business Cooperative Service

Agency Information Collection Activities: Revision of a Currently Approved Information Collection; Comments Request; Rural Development Loan Servicing

AGENCY: Rural Business-Cooperative Service, Agriculture (USDA).

ACTION: 60-Day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Business-Cooperative Service's (RBCS) intention to request a revision of a currently approved information collection in support of Rural Development Loan Servicing for the Intermediary Relending Program.

DATES: Comments on this notice must be received by October 12, 2021 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: Lori Pittman, Rural Business-Cooperative Service, USDA, STOP 3226, 1400 Independence Ave. SW, Washington, DC 20250–3226, Telephone: (202) 720–1400.

SUPPLEMENTARY INFORMATION:

Title: Rural Development Loan Servicing.

OMB Number: 0570–0015.

Expiration Date of Approval: November 30, 2021.

Type of Request: Revision of a currently approved information collection.

Abstract: Subpart R of 7 CFR part 1951 contains regulations for servicing and liquidating loans made by Rural Development under the Intermediary Relending Program (IRP) and the Rural Microentrepreneur Assistance Program (RMAP) to eligible intermediaries and applies to ultimate recipients and other involved parties. The information requested is vital to RBS for prudent loan servicing, credit decisions, and reasonable program monitoring.

Rural Development has determined that the financial reporting requirements are necessary to provide the Agency with current information in order to monitor the program, to make various reporting requirements to Congress, and for program innovation and expansion under the Government's Performance Review.

Servicing of the IRP is administered by RBCS in Washington, DC, which will be the primary user of the information collected. Under the Freedom of Information Act (FOIA), the general public can request the majority of the data by the Agency from the intermediaries, except for information that is classified as confidential.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 3 hours per response.

Respondents: Non-profit corporations, public agencies, Indian groups and cooperatives.

Estimated number of Respondents: 475.

Estimated number of responses: 3,941.

Estimated total annual burden on respondents: 11,878 hours.

Copies of this information collection can be obtained from Kimble Brown, Innovation Center—Regulations Management Division, at (202) 720–6780.

Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of RBCS, including whether the information will have practical utility; (b) the accuracy of RBCS estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Mark Brodziski,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 2021–17344 Filed 8–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket No. RBCS–BUSINESS–0025]

Notice of Request for Revisions of a Currently Approved Information Collection

AGENCY: Rural Business-Cooperative Service, Agriculture (USDA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Business-Cooperative Service's intention to request an extension for a currently approved information collection in support of the program Value-Added Producer Grants.

DATES: Comments on this notice must be received by October 12, 2021.

FOR FURTHER INFORMATION CONTACT: Robin M. Jones, Rural Development Innovation Center—Regulations Management Division, USDA, 1400 Independence Avenue SW, STOP 1522, Room 2445, South Building, Washington, DC 20250–1522. Telephone: (202) 772–1172. *Email: robin.m.jones@usda.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that RBCS is submitting to OMB as extension to an existing collection with Agency adjustment.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent by the Federal eRulemaking Portal: Go to *https://www.regulations.gov* and, in the ''Search'' box, type in the Docket No. RBS–21–BUSINESS–0026. A link to the Notice will appear. You may submit a comment here by selecting the ''Comment'' button or you can access the ''Docket'' tab, select the ''Notice,'' and go to the ''Browse & Comment on Documents'' Tab. Here you may view comments that have been submitted as well as submit a comment. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''FAQ'' link at the bottom. Comments on this information collection must be received by October 12, 2021.

Title: Value-Added Producer Grants.

OMB Number: 0570–0064.

Expiration Date of Approval: February 28, 2022.

Type of Request: Extension of a currently approved information collection.

Abstract: The purpose of this information collections to obtain information necessary to evaluate grant applications to determine the eligibility of the applicant and the project to determine which projects should be funded.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 39 hours per grant application.

Respondents: Independent producers, agriculture producer groups, farmer- or rancher-cooperatives, and majority controlled producer-based business ventures.

Estimated Number of Respondents: 470.

Estimated Number of Responses per Respondent: 11.

Estimated Number of Responses: 5,068.

Estimated Total Annual Burden on Respondents: 82,687 hours.

Copies of this information collection can be obtained from Robin M. Jones, Rural Development Innovation Center—Regulations Management Division, at (202) 772–1172. Email: *robin.m.jones@usda.gov.*

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Mark Brodziski,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2021–17294 Filed 8–12–21; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Application Materials for EDA Investment Assistance

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on May 27, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Economic Development Administration (EDA), Commerce.

Title: Application Materials for EDA Investment Assistance.

OMB Control Number: 0610–0094.

Form Number(s): ED–900, ED–900B, ED–900C, ED–900D, ED–900E, ED–900F.

Type of Request: Revision and extension of a currently approved information collection.

Number of Respondents: For construction projects, 977 estimated respondents, and for non-construction projects, 1,663 estimated respondents, for a total of *2,640* estimated respondents.

Average Hours per Response: For construction projects, 43.0 estimated hours per response, and for non-construction projects, 17.1 estimated hours per response.

Burden Hours: For construction projects, 42,011 estimated annual burden hours, and for non-construction projects, 28,437 estimated annual burden hours, for a total of *70,448* estimated total annual burden hours.

Application type	Estimated number of responses	Average time estimate	Total hours
Full Application Submission for Construction Applicants	977	43.0	42,011
Full Application Submission All Other EDA Programs	1,663	17.1	28,437

Application type	Estimated number of responses	Average time estimate	Total hours
Total	2,640		70,448

Needs and Uses: EDA must collect specific information from applicants for EDA investment assistance to evaluate whether proposed projects satisfy eligibility and programmatic requirements contained in EDA's authorizing legislation, the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3121 *et seq.*); EDA regulations at 13 CFR Chapter III; and applicable Notices of Funding Opportunity.

EDA proposes to revise and extend the following forms under this information collection: Forms ED–900 (General Application for EDA Programs), ED–900B (Beneficiary Information Form), ED–900C (EDA Application Supplement for Construction Programs), ED–900D (Requirements for Design and Engineering Assistance), ED–900E (Calculation of Estimated Relocation and Land Acquisition Expenses), and ED–900F (Additional EDA Assurances for Revolving Loan Fund Investments).

EDA does not propose to extend two existing forms under this information collection: Forms ED–900A (Additional EDA Assurances for Construction Or Non-Construction Investments and ED–900P (Proposal for EDA Assistance). Form ED–900A is no longer necessary because the assurances collected in Form ED–900A are redundant with other materials, including other forms under this information collection and certifications collected by *SAM.gov.* Form ED–900P is no longer necessary because EDA has removed the requirement for a financial assistance applicant to submit a proposal prior to submitting a full application. By eliminating Forms ED–900A and ED–900P, EDA will reduce the estimated time per response to this information collection.

Affected Public: Entities eligible for EDA financial assistance, including Federal, State, and local governments; Indian tribes; institutions of higher education; not-for-profit entities; and business or other for-profit organizations.

Frequency: During application for EDA investment assistance.

Respondent's Obligation: Mandatory.

Legal Authority: The Public Works and Economic Development Act of 1965 (42 U.S.C. 3121 et seq).

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0610–0094.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–17320 Filed 8–12–21; 8:45 am]

BILLING CODE 3510–34–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–831]

Seamless Refined Copper Pipe and Tube From the Socialist Republic of Vietnam: Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on the affirmative final determinations by the Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC), Commerce is issuing an antidumping duty (AD) order on seamless refined copper pipe and tube (copper pipe and tube) from the Socialist Republic of Vietnam (Vietnam).

DATES: Applicable August 13, 2021.

FOR FURTHER INFORMATION CONTACT: Ariela Garvett, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3609.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 735(d) and 777(i)(1) of the Tariff Act of 1930, as amended (the Act), on June 24, 2021, Commerce published its affirmative final determination of sales at less than fair value (LTFV) of copper pipe and tube from Vietnam.[1] As part of this determination, Commerce made negative critical circumstances findings for the sole mandatory respondent, Hailiang (Vietnam) Copper Manufacturing Company (Hailiang Vietnam) and its affiliated trading company Hongkong Hailiang Metal Trading Limited (also known as Hong Kong Hailiang Metal Trading Limited) (Hongkong Hailiang) (collectively, Hailiang Vietnam/Hongkong Hailiang), the non-examined, separate rate companies, and the Vietnam-wide entity.[2] On August 5, 2021, the ITC notified Commerce of its final affirmative determination that an industry in the United States is materially injured by reason of LTFV imports of copper pipe and tube from Vietnam, within the meaning of section 735(b)(1)(A)(i) of the Act.[3]

Scope of the Order

The products covered by this order are copper pipe and tube from Vietnam. For a complete description of the scope of the order, *see* the appendix to this notice.

Order

In accordance with sections 735(b)(1)(A)(i) and 735(d) of the Act, the ITC notified Commerce of its final determination that an industry in the United States is materially injured by reason of imports of copper pipe and tube from Vietnam.[4] Therefore, Commerce is issuing this order in accordance with section 735(c)(2) of the Act. Because Commerce has determined that sales of copper pipe and tube from Vietnam were made at LTFV, and the ITC determined that imports of copper pipe and tube from Vietnam are materially injuring a U.S. industry, unliquidated entries of such merchandise from Vietnam entered, or withdrawn from warehouse, for consumption are subject to the assessment of antidumping duties.

[1] *See Seamless Refined Copper Pipe and Tube from the Socialist Republic of Vietnam: Final Affirmative Determination of Sales at Less Than Fair Value, and Final Negative Determination of Critical Circumstances,* 86 FR 33228 (June 24, 2021) (*Final Determination*).

[2] *Id.*

[3] *See* ITC's Letter, ITC Notification, dated August 5, 2021 (ITC Notification).

[4] *Id.*

In accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the subject merchandise for all relevant entries of copper pipe and tube from Vietnam. Antidumping duties will be assessed on unliquidated entries of copper pipe and tube from Vietnam entered, or withdrawn from warehouse, for consumption on or after February 1, 2021, the date of publication of the *Preliminary Determination,*[5] but antidumping duties will not be assessed on entries of subject merchandise occurring after the expiration of the provisional measures period and before publication in the **Federal Register** of the ITC's final injury determination, as further described below.

Continuation of Suspension of Liquidation

In accordance with section 736 of the Act, Commerce will instruct CBP to continue to suspend liquidation on all relevant entries of copper pipe and tube from Vietnam entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's final affirmative injury determination in the **Federal Register**. These instructions suspending liquidation will remain in effect until further notice.

Pursuant to 735(c)(1)(B) of the Act and 19 CFR 351.210(d), Commerce will also instruct CBP to require cash deposits equal to the appropriate estimated weighted-average dumping margin indicated in the table below. Accordingly, effective on the date of publication of the ITC's final affirmative injury determination, CBP will require, at the same time as an importer of record would normally deposit estimated duties on the subject merchandise, a cash deposit for each entry of subject merchandise equal to the appropriate estimated weighted-average dumping margins listed below.[6]

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

Exporter	Producer	Estimated weighted-average dumping margin (percent)
Hailiang (Vietnam) Copper Manufacturing Company Limited/Hongkong Hailiang Metal Trading Limited (aka Hong Kong Hailiang Metal Trading Limited).	Hailiang (Vietnam) Copper Manufacturing Company Limited/Hongkong Hailiang Metal Trading Limited (aka Hong Kong Hailiang Metal Trading Limited).	8.35
Jintian Copper Industrial (Vietnam) Company Limited (aka Jintian Copper Industrial (Vietnam) Co., Ltd).	Jintian Copper Industrial (Vietnam) Company Limited (aka Jintian Copper Industrial (Vietnam) Co., Ltd).	8.35
Toan Phat Copper Tube Joint Stock Company	Toan Phat Copper Tube Joint Stock Company	8.35
Vietnam-Wide Entity		8.35

Provisional Measures

Section 733(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except that Commerce may extend the four-month period to no more than six months at the request of exporters representing a significant proportion of exports of the subject merchandise. Commerce published its affirmative *Preliminary Determination* on February 1, 2021.[7] On February 8, 2021, Commerce postponed the *Final Determination* and extended the provisional measures period from four months to six months.[8] Commerce published the *Final Determination* in the **Federal Register** on June 24, 2021.[9] The six-month period beginning on the date of publication of the LTFV *Preliminary Determination* ended on July 30, 2021.

Therefore, in accordance with section 733(d) of the Act, Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of copper pipe and tube from Vietnam, entered, or withdrawn from warehouse, for consumption after July 30, 2021, the date on which the provisional measures expired, through the day preceding the date of publication of the ITC's final affirmative injury determination in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final determination in the **Federal Register**.

Notification to Interested Parties

This notice constitutes the AD order with respect to copper pipe and tube from Vietnam pursuant to section 736(a) of the Act. Interested parties can find a list of AD orders currently in effect at *https://enforcement.trade.gov/stats/iastats1.html.*

This order is published in accordance with section 736(a) of the Act and 19 CFR 351.211(b).

Dated: August 9, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Order

The products covered by this order are all seamless circular refined copper pipes and tubes, including redraw hollows, greater than or equal to 6 inches (152.4 mm) in actual length and measuring less than 12.130 inches (308.102 mm) in actual outside diameter (OD), regardless of wall thickness, bore (*e.g.,* smooth, enhanced with inner grooves or ridges), manufacturing process (*e.g.,* hot finished, cold-drawn, annealed), outer surface (*e.g.,* plain or enhanced with grooves, ridges, fins, or gills), end finish (*e.g.,* plain end, swaged end, flared end, expanded end, crimped end, threaded), coating (*e.g.,* plastic, paint), insulation, attachments (*e.g.,* plain, capped, plugged, with compression or other fitting), or physical configuration (*e.g.,* straight, coiled, bent, wound on spools).

The scope of this order covers, but is not limited to, seamless refined copper pipe and tube produced or comparable to the American Society for Testing and Materials

[5] *See Seamless Refined Copper Pipe and Tube from the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Preliminary Negative Determination of Critical Circumstances,* 86 FR 7698 (February 1, 2021) (*Preliminary Determination*).

[6] *See* section 736(a)(3) of the Act.

[7] *See Preliminary Determination.*

[8] *See Seamless Refined Copper Pipe and Tube from the Socialist Republic of Vietnam: Postponement of Final Determination in the Less-Than-Fair-Value Investigation,* 86 FR 8588 (February 8, 2021).

[9] *See Final Determination.*

(ASTM) ASTM–B42, ASTM–B68, ASTM–B75, ASTM–B88, ASTM–B88M, ASTM–B188, ASTM–B251, ASTM–B251M, ASTM–B280, ASTM–B302, ASTM–B306, ASTM–B359, ASTM–B743, ASTM–B819, and ASTM–B903 specifications and meeting the physical parameters described therein.

Also included within the scope of this order are all sets of covered products, including ''line sets'' of seamless refined copper tubes (with or without fittings or insulation) suitable for connecting an outdoor air conditioner or heat pump to an indoor evaporator unit. The phrase ''all sets of covered products'' denotes any combination of items put up for sale that is comprised of merchandise subject to the scope.

''Refined copper'' is defined as: (1) Metal containing at least 99.85 percent by actual weight of copper; or (2) metal containing at least 97.5 percent by actual weight of copper, provided that the content by actual weight of any other element does not exceed the following limits:

Element	Limiting content percent by weight
Ag—Silver	0.25
As—Arsenic	0.5
Cd—Cadmium	1.3
Cr—Chromium	1.4
Mg—Magnesium	0.8
Pb—Lead	1.5
S—Sulfur	0.7
Sn—Tin	0.8
Te—Tellurium	0.8
Zn—Zinc	1.0
Zr—Zirconium	0.3
Other elements (each)	0.3

Excluded from the scope of this order are all seamless circular hollows of refined copper less than 12 inches in actual length whose actual OD exceeds its actual length.

The products subject to this order are currently classifiable under subheadings 7411.10.1030 and 7411.10.1090 of the Harmonized Tariff Schedule of the United States (HTSUS). Products subject to the order may also enter under HTSUS subheadings 7407.10.1500, 7419.99.5050, 8415.90.8065, and 8415.90.8085. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

[FR Doc. 2021–17375 Filed 8–12–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB313]

Permanent Advisory Committee To Advise the U.S. Commissioners to the Western and Central Pacific Fisheries Commission; Meeting Announcement

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: NMFS announces a public meeting of the Permanent Advisory Committee (PAC) to advise the U.S. Commissioners to the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC) on October 13–15, 2021. Meeting topics are provided under the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: The meeting of the PAC will be held on October 13, 2021, from 10 a.m. to 1 p.m. Hawaii Standard Time (HST) (or until business is concluded), October 14, 2021, from 10 a.m. to 1 p.m. HST (or until business is concluded), and October 15, 2021, from 10 a.m. to 1 p.m. HST (or until business is concluded). Members of the public may submit written comments on meeting topics or materials; comments must be received by October 8, 2021.

ADDRESSES: The public meeting will be conducted via a web conference. For details on how to join the web conference, call in, or to submit comments, please contact Emily Reynolds, NMFS Pacific Islands Regional Office; telephone: 808–725–5039; email: *emily.reynolds@noaa.gov*. Documents to be considered by the PAC will be sent out via email in advance of the web conference. Please submit contact information to Emily Reynolds (telephone: 808–725–5039; email: *emily.reynolds@noaa.gov*) at least 3 days in advance of the web conference to receive documents via email. This meeting may be recorded for the purposes of generating notes of the meeting and participation in the web conference constitutes consent to the recording.

FOR FURTHER INFORMATION CONTACT: Emily Reynolds, NMFS Pacific Islands Regional Office; 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818; telephone: 808–725–5039; facsimile: 808–725–5215; email: *emily.reynolds@noaa.gov*.

SUPPLEMENTARY INFORMATION: In accordance with the Western and Central Pacific Fisheries Convention Implementation Act (16 U.S.C. 6901 *et seq.*), the PAC has been formed to advise the U.S. Commissioners to the WCPFC. The PAC is composed of: (i) Not less than 15 nor more than 20 individuals appointed by the Secretary of Commerce in consultation with the U.S. Commissioners to the WCPFC; (ii) the chair of the Western Pacific Fishery Management Council's Advisory Committee (or the chair's designee); and (iii) officials from the fisheries management authorities of American Samoa, Guam, and the Northern Mariana Islands (or their designees). The PAC supports the work of the U.S. National Section to the WCPFC in an advisory capacity. The U.S. National Section is made up of the U.S. Commissioners and the Department of State. NMFS Pacific Islands Regional Office provides administrative and technical support to the PAC in cooperation with the Department of State. More information on the WCPFC, established under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean, can be found on the WCPFC website: *http://www.wcpfc.int.*

Meeting Topics

The PAC meeting topics may include the following: (1) Outcomes of the 2020 annual session of the WCPFC and 2021 sessions of the WCPFC Scientific Committee, Northern Committee, and Technical and Compliance Committee; (2) issues to be considered in the WCPFC 2021 annual session; (3) potential U.S. proposals to the WCPFC 2021 annual session; and (4) other issues.

Special Accommodations

The web conference is accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Emily Reynolds at 808–725–5039 by September 29, 2021.

Authority: 16 U.S.C. 6902 *et seq.*

Dated: August 10, 2021.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–17356 Filed 8–12–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB309]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of issuance of Letter of Authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, its implementing regulations, and NMFS' MMPA Regulations for Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico, notification is hereby given that a Letter of Authorization (LOA) has been issued to Taylor Energy Company LLC (Taylor) for the take of marine mammals incidental to geophysical survey activity in the Gulf of Mexico.

DATES: The LOA is effective from August 15, 2021, through August 15, 2022.

ADDRESSES: The LOA, LOA request, and supporting documentation are available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

On January 19, 2021, we issued a final rule with regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively ''industry operators''), in Federal waters of the U.S. Gulf of Mexico (GOM) over the course of 5 years (86 FR 5322; January 19, 2021). The rule was based on our findings that the total taking from the specified activities over the 5-year period will have a negligible impact on the affected species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of those species or stocks for subsistence uses. The rule became effective on April 19, 2021.

Our regulations at 50 CFR 217.180 *et seq.* allow for the issuance of LOAs to industry operators for the incidental take of marine mammals during geophysical survey activities and prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat (often referred to as mitigation), as well as requirements pertaining to the monitoring and reporting of such taking. Under 50 CFR 217.186(e), issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a determination that the amount of take authorized under the LOA is of no more than small numbers.

Summary of Request and Analysis

Taylor plans to conduct a 2D high resolution seismic survey in Mississippi Canyon Block 20. Taylor plans to use a single, 10-cubic inch airgun, and would also use a suite of high-resolution geophysical acoustic sources aboard an autonomous underwater vehicle. Please see Taylor's application for additional detail.

Consistent with the preamble to the final rule, the survey effort proposed by Taylor in its LOA request was used to develop LOA-specific take estimates based on the acoustic exposure modeling results described in the preamble (86 FR 5322, 5398; January 19, 2021). In order to generate the appropriate take number for authorization, the following information was considered: (1) Survey type; (2) location (by modeling zone [1]); (3) number of days; and (4) season.[2] The acoustic exposure modeling performed in support of the rule provides 24-hour exposure estimates for each species, specific to each modeled survey type in each zone and season.

Exposure modeling results were generated using the single airgun proxy. Because those results assume use of a 90-in^3 airgun, the take numbers authorized through this LOA are considered conservative (*i.e.,* they likely overestimate take) due to differences in the sound source planned for use by Taylor, as compared to those modeled for the rule. The survey is planned to occur for 3 days in Zone 5. The season is not known in advance. Therefore, the take estimates for each species are based on the season that has the greater value for the species (*i.e.,* winter or summer).

In this case, use of the exposure modeling produces results that are substantially smaller than average GOM group sizes for multiple species (*i.e.,* estimated exposure values are less than 10 percent of assumed average group size for the majority of species) (Maze-Foley and Mullin, 2006). NMFS' typical practice in such a situation is to increase exposure estimates to the assumed average group size for a species in order to ensure that, if the species is encountered, exposures will not exceed the authorized take number. However, other relevant considerations here lead to a determination that increasing the estimated exposures to average group

[1] For purposes of acoustic exposure modeling, the GOM was divided into seven zones. Zone 1 is not included in the geographic scope of the rule.

[2] For purposes of acoustic exposure modeling, seasons include Winter (December–March) and Summer (April–November).

sizes would likely lead to an overestimate of actual potential take. In this circumstance, the very short survey duration and relatively small Level B harassment isopleths produced through use of a single airgun (compared with an airgun array) mean that it is unlikely that certain species would be encountered at all, much less that the encounter would result in exposure of a greater number of individuals than is estimated through use of the exposure modeling results. As a result, in this case NMFS has not increased the estimated exposure values to assumed average group sizes in authorizing take.

Based on the results of our analysis, NMFS has determined that the level of taking expected for this survey and authorized through the LOA is consistent with the findings made for the total taking allowable under the regulations. See Table 1 in this notice and Table 9 of the rule (86 FR 5322; January 19, 2021).

Small Numbers Determination

Under the GOM rule, NMFS may not authorize incidental take of marine mammals in an LOA if it will exceed ''small numbers.'' In short, when an acceptable estimate of the individual marine mammals taken is available, if the estimated number of individual animals taken is up to, but not greater than, one-third of the best available abundance estimate, NMFS will determine that the numbers of marine mammals taken of a species or stock are small. For more information please see NMFS' discussion of the MMPA's small numbers requirement provided in the final rule (86 FR 5322, 5438; January 19, 2021).

The take numbers for authorization, which are determined as described above, are used by NMFS in making the necessary small numbers determinations, through comparison with the best available abundance estimates (see discussion at 86 FR 5322, 5391; January 19, 2021). For this comparison, NMFS' approach is to use the maximum theoretical population, determined through review of current stock abundance reports (SAR; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and model-predicted abundance information (*https://seamap.env.duke.edu/models/Duke/GOM/*). For the latter, for taxa where a density surface model could be produced, we use the maximum mean seasonal (*i.e.,* 3-month) abundance prediction for purposes of comparison as a precautionary smoothing of month-to-month fluctuations and in consideration of a corresponding lack of data in the literature regarding seasonal distribution of marine mammals in the GOM. Information supporting the small numbers determinations is provided in Table 1.

TABLE 1—TAKE ANALYSIS

Species	Authorized take [1]	Abundance [2]	Percent abundance
Rice's whale [3]	0	51	n/a
Sperm whale	2	2,207	0.1
Kogia spp.	1	4,373	0.0
Beaked whales	47	3,768	1.2
Rough-toothed dolphin	1	4,853	0.0
Bottlenose dolphin	5	176,108	0.0
Clymene dolphin	2	11,895	0.0
Atlantic spotted dolphin	2	74,785	0.0
Pantropical spotted dolphin	10	102,361	0.0
Spinner dolphin	3	25,114	0.0
Striped dolphin	1	5,229	0.0
Fraser's dolphin	0	1,665	n/a
Risso's dolphin	1	3,764	0.0
Melon-headed whale	2	7,003	0.0
Pygmy killer whale	0	2,126	n/a
False killer whale	1	3,204	0.0
Killer whale	0	267	n/a
Short-finned pilot whale	0	1,981	n/a

[1] Scalar ratios were not applied in this case due to brief survey duration.

[2] Best abundance estimate. For most taxa, the best abundance estimate for purposes of comparison with take estimates is considered here to be the model-predicted abundance (Roberts *et al.,* 2016). For those taxa where a density surface model predicting abundance by month was produced, the maximum mean seasonal abundance was used. For those taxa where abundance is not predicted by month, only mean annual abundance is available. For the killer whale, the larger estimated SAR abundance estimate is used.

[3] The final rule refers to the GOM Bryde's whale (*Balaenoptera edeni*). These whales were subsequently described as a new species, Rice's whale (*Balaenoptera ricei*) (Rosel *et al.,* 2021).

Based on the analysis contained herein of Taylor's proposed survey activity described in its LOA application and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the affected species or stock sizes (*i.e.,* less than one-third of the best available abundance estimate) and therefore the taking is of no more than small numbers.

Authorization

NMFS has determined that the level of taking for this LOA request is consistent with the findings made for the total taking allowable under the incidental take regulations and that the amount of take authorized under the LOA is of no more than small numbers. Accordingly, we have issued an LOA to Taylor authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Dated: August 10, 2020.

Catherine Marzin,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–17329 Filed 8–12–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB326]

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of receipt of one enhancement permit application and request for comment.

SUMMARY: Notice is hereby given that NMFS has received one permit application submitted by California Department of Fish and Wildlife (CDFW) to enhance the propagation and survival of species listed under the Endangered Species Act (ESA) of 1973, as amended, for a 5-year period. This document serves to notify the public of the availability of the permit application for review and comment, prior to a decision by NMFS whether to issue the permit.

DATES: Comments or requests for a public hearing on the application must be received at the appropriate address (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on September 13, 2021.

ADDRESSES: The permit application may be viewed online at: *https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.* Written comments on the application should be submitted to the NMFS California Central Valley Office, 650 Capitol Mall, Suite 5–100, Sacramento, CA 95814. Comments may also be submitted by email to *amanda.cranford@noaa.gov* (include the permit number in the subject line of the email).

FOR FURTHER INFORMATION CONTACT: Amanda Cranford, Sacramento, CA (Phone: 916–930–3706; Email: *amanda.cranford@noaa.gov*). Permit application instructions are available from the address above, or online at *https://apps.nmfs.noaa.gov*.

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Chinook salmon (Oncorhynchus tshawytscha): Threatened, naturally produced and hatchery propagated Sacramento River winter-run;

Chinook salmon (Oncorhynchus tshawytscha): Threatened, naturally produced and hatchery-propagated Central Valley (CV) spring-run;

Steelhead (O. mykiss): Threatened, naturally produced and artificially propagated California Central Valley (CCV).

North American green sturgeon (Acipenser medirostris): Threatened, naturally produced southern distinct population segment (sDPS).

Background

Permit 18181–4R

CDFW is seeking to renew an enhancement permit under section 10(a)(1)(A) of the ESA for a period of 5 years that would allow take of both adult and juvenile Sacramento River winter-run Chinook salmon, CV spring-run Chinook salmon, CCV steelhead, and sDPS North American green sturgeon in the Sacramento River and its tributaries. This permit renewal would cover four monitoring and rescue efforts carried out by CDFW: (1) Juvenile emigration monitoring, (2) adult trapping for the Steelhead Monitoring Program, (3) Upper Sacramento River restoration site monitoring, and (4) fish salvage and rescue operations.

Each project has its own objectives. The Juvenile Emigration Monitoring will take place at Tisdale Weir, Knights Landing, the Feather River High Flow Channel, and the Delta Entry sites, with the goals to monitor juvenile salmonid outmigration in real time, provide summaries of timing, abundance, and size distribution, provide timing information to water agencies for better management decisions, and evaluate how environmental conditions (flow, temperature, turbidity) affect downstream movement. The objectives of the Central Valley Steelhead Monitoring will be conducted to estimate the steelhead population abundance, examine trends in abundance, and identify spatial distribution over time. The Upper Sacramento River Restoration Site Monitoring aims to evaluate the outcome of the Central Valley Project Improvement Act Section 3406(b)(13) gravel augmentation and restoration projects through documentation of spawning activity, relative abundance of juvenile salmonids using the restored habitat, habitat attributes and quantities in restored sites, and habitat conditions and fish presence in control and pre- and post-construction sites. Efforts associated with the Central Valley Fish Rescues will involve the collection, tagging, and relocation of entrained listed salmonids and sDPS green sturgeon at the fish collection facility at Wallace Weir, the Colusa Basin Drainage Canal, behind Fremont and Tisdale weirs, the Sacramento River, Deer Creek, Mill Creek, Antelope Creek, and various urban streams. The rescue program also assesses the magnitude of stranding and aims to document conditions resulting in high levels of stranding. CDFW staff will also monitor winter-run Chinook salmon redds that are at risk of being dewatered. In the event that a redd is likely to be dewatered, CDFW staff may physically modify the redd by hand to prevent complete dewatering and increase the likelihood of survival.

Under the various studies, juvenile salmonids and smolts would be observed via snorkel and video surveys and captured using rotary screw traps and beach seines. In addition, juvenile salmonids would be handled: Anesthetized, measured, checked for marks or tags, tagged (acoustic tags for spring-run Chinook salmon, passive integrated transponder (PIT) tags for steelhead, and elastomer tags for salmonids used during rotary screw trap efficiency trials), sampled for tissues, and released. A subsample of hatchery-origin (adipose fin clipped) winter-run Chinook salmon and spring-run Chinook salmon juveniles and smolts would be sacrificed for coded wire tag (CWT) retrieval and analysis. In the case of rescues and relocations, fish may be collected and transported (either via foot or transport truck, depending on the distance to the release location) to more suitable habitat prior to release.

Adult salmonids would be observed via snorkel, video, or spawning surveys and captured using beach seines, fish weirs, and fyke traps. Adult steelhead may also be captured in rotary screw traps. In addition, adult salmonids would be handled as follows: anesthetized, measured, checked for marks or tags, tagged (floy tags for all adult salmonids, as well as PIT tags for steelhead, and acoustic tags for both spring- and winter-run Chinook salmon), sampled for tissues, and released. Tissues would be collected from any carcasses encountered.

Juvenile, subadult, and adult green sturgeon would be captured via hoop nets and fyke traps, anesthetized, tissue sampled, tagged (PIT or acoustic), and released. Additionally, juvenile green sturgeon may be captured in rotary screw traps and adults may be encountered during monitoring at weirs. Subadult and adult green sturgeon would also receive floy tags. Adult sturgeon may also be collected and transported live to more suitable habitat during rescue activities.

With the exception of the juvenile salmon CWT retrieval (above), the researchers are not proposing to kill any of the fish being captured, but a small number of fish may be incidentally killed as an inadvertent result of these

activities. However, fish captured and relocated as part of the fish rescues would likely perish due to low flows and dissolved oxygen, coupled with high water temperatures, if it were not for this project.

The proposed projects could impact ESA-listed species by delaying migration, resulting in stress, or indirect mortality or indirect non-lethal effects as a result of stress, physical harm during insertion of tags, and/or susceptibility to predation upon displacement at release. These effects will be minimized by frequent (at least daily) trap checks and taking all possible measures to expedite the process of capturing, tagging, and releasing adult entrained fish. Anesthetization will follow strict guidelines and use the least amount of sedative necessary. Unintentional mortality of juvenile fish can occur during rotary screw trapping and will be minimized through a reduction in sampling effort or through increased checking/servicing of rotary-screw traps.

Authority

Enhancement permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR part 222). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; (3) are consistent with the purposes and policies of section 2 of the ESA; (4) further a bona fide and necessary or desirable scientific purpose or enhance the propagation or survival of the endangered species, taking into account the benefits anticipated to be derived on behalf of the endangered species; and additional issuance criteria as listed at 50 CFR 222.308(c)(5–12). The authority to take listed species is subject to conditions set forth in the permit.

Anyone requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Public Comments Solicited

NMFS invites the public to comment on the section 10(a)(1)(A) enhancement permit application during a 30-day public comment period beginning on the date of this notice. This notice is provided pursuant to section 10(c) of the ESA (16 U.S.C. 1529(c)). All comments and materials received, including names and addresses, will become part of the administrative record and may be released to the public. We provide this notice in order to allow the public, agencies, or other organizations to review and comment on these documents.

Next Steps

NMFS will evaluate the permit application, associated documents, and comments submitted to determine whether the applications meet the requirements of section 10(a)(1)(A) of the ESA and the applicable Federal regulations. The final permit decisions will not be made until after the end of the 30-day public comment period and after NMFS has fully considered all relevant comments received. NMFS will publish notice of its final action in the **Federal Register**.

Dated: August 10, 2021.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–17401 Filed 8–12–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB323]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Ecosystem Subcommittee of the Scientific and Statistical Committee (SSC) will hold an online meeting to review new analyses conducted by the NMFS California Current Integrated Ecosystem Assessment team that may potentially inform future annual reports to the Pacific Council on the state of the California Current Ecosystem.

DATES: The online meeting will be held Tuesday, August 31, 2021, from 1 p.m. to 5 p.m. Pacific Daylight Time (PDT). The online meeting will reconvene on Wednesday, September 1, 2021, from 8:30 a.m. to 12:30 p.m. PDT.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: John DeVore, Staff Officer, Pacific Council; telephone: (503) 820–2413.

SUPPLEMENTARY INFORMATION: The SSC's Ecosystem Subcommittee will review analyses conducted by the NMFS California Current Integrated Ecosystem Assessment team. Specifically, the SSC Ecosystem Subcommittee will review the following four items: (1) Threshold Relationships Between Environmental Drivers and Performance of Salmon Preseason Abundance Forecasts, (2) Krill-based Indicators, (3) Year Class Strength and Distribution of Small Groundfish, and (4) Port-level Linkages Between Fisheries using Network Analysis. The SSC's Ecosystem Subcommittee will consider recommending summaries of these ecosystem indicators be included in future state of the California Current Ecosystem reports to the Pacific Council.

No management actions will be decided by the SSC's Ecosystem Subcommittee. The SSC Ecosystem Subcommittee members' role will be development of recommendations and a report for consideration by the SSC and Pacific Council at their March 2022 meeting in San Jose, CA.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 9, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–17289 Filed 8–12–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB288]

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; Determination on Hatchery and Genetic Management Plan (HGMP) and availability of the associated Finding of No Significant Impacts (FONSI).

SUMMARY: Notice is hereby given that NMFS has made a determination on a joint tribal and state resource management plan (RMP) pursuant to Limit 6 of the Endangered Species Act (ESA) section 4(d) and has issued a Final Environmental Assessment (EA) and FONSI addressing the effects of the 4(d) determination. The Tulalip Tribes and Washington Department of Fish and Wildlife (collectively the co-managers) have submitted an RMP, in the form of a HGMP, to NMFS pursuant to limit 6 of the ESA 4(d) Rule for a summer steelhead hatchery program in the Skykomish River basin. The hatchery program is intended to contribute to fulfilling Federal tribal trust responsibilities and treaty rights guaranteed through treaties. It is also designed to contribute to the survival and recovery of Puget Sound steelhead and produce summer steelhead for sustainable fisheries. Before making its final determinations, NMFS solicited and took into account public comments on a proposed evaluation and pending determination (PEPD) document for the program. The determinations announced in this notice consist of NMFS' findings as to whether the HGMP submitted to NMFS addresses the criteria. NMFS also announces the availability of a Final EA and FONSI addressing the effects of the 4(d) determination.

FOR FURTHER INFORMATION CONTACT: Emi Melton, at phone number: (503) 736–4739, or via email: *emi.melton@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

Steelhead (*Oncorhynchus mykiss*): threatened, naturally produced and artificially propagated Puget Sound.

Chinook salmon (*O. tshawytscha*): threatened, naturally produced and artificially propagated Puget Sound.

Discussion of the Biological Analysis Underlying the Determinations

The goals of the Skykomish summer steelhead program are: (1) To produce South Fork Skykomish River summer steelhead for sustainable fisheries, (2) to contribute to fulfilling Federal tribal trust responsibilities and treaty rights guaranteed through treaties and affirmed in *U.S.* v. *Washington* (1974), and (3) to contribute to the conservation and restoration of the North Fork Skykomish River summer steelhead population.

The program would be operated in such a way as to minimize potential risks to listed natural-origin Chinook salmon and steelhead populations, including interactions between hatchery and natural fish that may lead to adverse genetic effects and competition and predation effects. The proposed hatchery program is consistent with the recovery plans for each of the listed species, designed to protect and restore listed species across their range. The program uses adaptive management procedures and the best available science to minimize adverse genetic effects typically associated with steelhead hatchery programs. As part of the proposed hatchery program, monitoring and evaluation would be implemented to assess performance in meeting population conservation or harvest augmentation objectives, and to evaluate effects on ESA-listed natural-origin Chinook salmon and steelhead. Information gained through monitoring and evaluation will be used to assess whether the impacts of the program on listed fish are as expected.

Review of monitoring and evaluation results by NMFS and the co-managers will occur annually to evaluate whether assumptions regarding the hatchery program effects and analysis remain valid and whether the objectives are being accomplished. The HGMP includes provisions for annual reports that will assess compliance with performance standards established through the HGMP. Reporting and inclusion of new information derived from HGMP's research, monitoring, and evaluation activities will allow for adjustments of the activities to meet the performance standards in future seasons.

Summary of Comments Received

NMFS published a notice of its PEPD on the Skykomish Summer Steelhead Program for public review and comment on December 22, 2020 (85 FR 83519), as required under Limit 6 of the ESA section 4(d) Rule. The PEPD was available for public review and comment for 30 days, and our responses to the comments are addressed in our Evaluation and Recommended Determination.

NMFS published a notice of availability for public review and comment on the Draft EA on February 5, 2021 (86 FR 8342), in accordance with National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*). The Draft EA was available for public review and comment for 30 days, and our responses to the comments are addressed in our Final EA. NMFS has determined that there are no significant impacts associated with the project and issued a FONSI for the program on July 2, 2021.

Authority

16 U.S.C. 1531–1543; 50 CFR subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for 50 CFR 223.206(d)(9).

Dated: August 10, 2021.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–17381 Filed 8–12–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; NTIA Internet Use Survey

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on May 25, 2021 during a 60-day comment period.

This notice allows for an additional 30 days for public comments.

Agency: National Telecommunications and Information Administration, Commerce.

Title: NTIA internet Use Survey.

OMB Control Number: 0660–0021.

Form Number(s): None.

Type of Request: Regular submission (Revision of a current information collection).

Number of Respondents: 54,000 households.

Estimated Time per Response: 10 minutes.

Burden Hours: 9,000.

Needs and Uses: Data from the NTIA internet Use Survey will be used to help inform federal policies related to digital equity and other internet-related issues. NTIA will use the data both in relevant publications and to help inform policymakers. Additionally, a public use dataset that protects respondent confidentiality will be created by the Census Bureau and made available by both agencies for use by researchers and other members of the public.

Affected Public: Individuals and households.

Frequency: Biennial.

Respondent's Obligation: Voluntary.

Legal Authority: 47 U.S.C. 902(b)(2)(M), (P).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0660–0021.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–17379 Filed 8–12–21; 8:45 am]

BILLING CODE 3510–60–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes product(s) and service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to and deleted from the Procurement List:* September 12, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION:

Deletions

On 7/9/2021, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s): 7520–01–383–7929—Marker, Tube Type, Highlighter, Chisel Tip, Magenta

Designated Source of Supply: Dallas Lighthouse for the Blind, Inc., Dallas, TX

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR (2, NEW YORK, NY

Service(s)

Service Type: Document Destruction

Mandatory for: Defense Logistics Agency, Defense Supply Center, Columbus, OH, 3990 East Broad Street, Columbus, OH

Designated Source of Supply: Greene, Inc., Xenia, OH

Contracting Activity: DEFENSE LOGISTICS AGENCY, DCSO COLUMBUS

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2021–17373 Filed 8–12–21; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete products and services from Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: September 12, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785- 6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) and service(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
MR 13025—Set, Disc, Christmas
MR 13049—Set, Disc, Springtime
MR 13004—Greensaver Crisper Insert
MR 13009—Salad Chopper with Bowl

Designated Source of Supply: Cincinnati Association for the Blind, Cincinnati, OH

Contracting Activity: Military Resale-Defense

Commissary Agency
NSN(s)—Product Name(s):
MR 3232—So Fabulous Monofiliment Brush
MR 3235—Ponytailers Girls
*Designated Source of Supply: A*ssociation for Vision Rehabilitation and Employment, Inc., Binghamton, NY
Contracting Activity: Military Resale-Defense Commissary Agency

Service(s)

Service Type: Medical Transcription
Mandatory for: Veterans Affairs Medical Center, Alexandria, LA
Designated Source of Supply: Lighthouse for the Blind of Houston, Houston, TX
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, NAC

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2021–17371 Filed 8–12–21; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Intent To Prepare a Supplemental Environmental Impact Statement to the 2014 Final Integrated Feasibility Report and Environmental Impact Statement for the West Shore Lake Pontchartrain Hurricane and Storm Damage Risk Reduction Study, St. Charles, St. James, and St. John the Baptist Parishes

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The U.S. Army Corps of Engineers (USACE), Mississippi Valley Division, New Orleans District (CEMVN), is announcing its intent to prepare a Supplemental Environmental Impact Statement (SEIS) to reevaluate alternatives to compensate for unavoidable impacts to swamp habitat associated with the construction of the West Shore Lake Pontchartrain Hurricane and Storm Damage Risk Reduction Project (hereafter WSLP Project). Compensatory mitigation for impacts due to construction of the WSLP Project was described previously in the 2014 WSLP Environmental Impact Statement (EIS) and in Environmental Assessment (EA) 576, which addressed mitigation for habitat impacts associated with each of CEMVN's Bipartisan Budget Act (BBA) of 2018 funded risk reduction projects (*i.e.,* the WSLP Project, Comite River Diversion Project, and the East Baton Rouge Parish Watershed Flood Risk Management Project). The Finding of No Significant Impact (FONSI) for EA 576 was signed by the CEMVN District Commander on April 4, 2020. Public comment on EA 576 included requests by the Louisiana's Coastal Protection Restoration Authority (CPRA) and others that the Mississippi River Diversion into Maurepas Swamp Project (hereafter MSP), a proposed ecological restoration project that shares construction features with the WSLP Project, be considered as a mitigation alternative for impacts to swamp habitat associated with the construction of the WSLP Project. Anticipated impacts to swamp habitat as a result of the construction of the MSP, estimated to be approximately 55 Average Annual Habitat Units (AAHU), would be self-mitigated by the operation of the diversion. Impacts to bottom land hardwood (BLH) habitat because of the MSP construction would be approximately 30 AAHU. These BLH impacts would be mitigated in accordance with EA 576.

ADDRESSES: U.S. Army Corps of Engineers, New Orleans District, Attn: CEMVN–PDC–C, 7400 Leake Avenue, New Orleans, Louisiana, 70118.

FOR FURTHER INFORMATION CONTACT: Questions and scoping comments regarding the proposed action should be directed to Mr. Landon Parr at U.S. Army Corps of Engineers, New Orleans District, Attn: CEMVN–PDC–C, 7400 Leake Avenue, New Orleans, Louisiana 70118, by phone (504) 862–1908, or by email at *Landon.Parr@usace.army.mil.* For additional information, including but not limited to a copy of 2014 WSLP EIS, and other associated documents, please visit the WSLP Project website at: *https://www.mvn.usace.army.mil/Missions/Environmental/NEPA-Compliance-Documents/Bipartisan-Budget-Act-2018-BBA-18/West-Shore-Lake-Pontchartrain/.*

SUPPLEMENTARY INFORMATION:

1. Project Details. The WSLP Project is located in southeast Louisiana on the east-bank of the Mississippi River in St. Charles, St. John the Baptist, and St. James Parishes. Part of the Water Infrastructure Improvement for the Nation Act (WIIN Act, Pub. L. 114–322) in 2016 authorized construction of the WSLP Project. The BBA of 2018 (BBA 2018, Pub. L. 115–123) funded construction of the WSLP Project. The WSLP Project is described in the 2014 WSLP EIS; West Shore Lake Pontchartrain Hurricane and Storm Damage Risk Reduction Structural Alignment Surveys and Borings Investigations St. Charles and St. John the Baptist Parishes, Louisiana Supplemental Environmental Assessment (SEA) 570; and West Shore Lake Pontchartrain Hurricane and Storm Damage Risk Reduction Levee System, St. Charles and St. John the Baptist Parishes, Louisiana SEA 571. The WSLP Project is approximately 19 miles in length and includes approximately 18 miles of levee, one mile of T-wall, six pumping stations with associated drainage structures, one gated road crossing, two gated railroad crossings, and approximately 35 utility relocations.

The Record of Decision (ROD) for the 2014 WSLP EIS was signed by the Assistant Secretary of the Army, Civil Works on September 14, 2016. SEA 570 investigated levee alignment shifts as well as the addition of five stockpile/staging areas for construction related activities. The FONSI associated with SEA 570 was signed by the CEMVN District Commander on May 13, 2019. SEA 571 evaluated additional changes to the WSLP levee alignment, the addition of four borrow areas, widening of the levee alignment, minor modifications to previously assessed access roads, and the addition of three access roads. The FONSI associated with SEA 571 was signed by the CEMVN District Commander on June 29, 2020.

Based on the changes to date, the WSLP Project could impact approximately 10,895 acres of swamp and 4,880 acres of wetland bottomland hardwoods (BLH-Wet) in the Louisiana (LA) Coastal Zone (CZ). This equates to a compensatory mitigation need of approximately 1,010 AAHU of CZ swamp (if the MSP is selected) [including direct impacts to swamp associated with construction of the MSP (~55 AAHU), and direct (~600 AAHU) and indirect (~355 AAHU) impacts to swamp associated with the construction of WSLP] and approximately 295 AAHU of CZ BLH-Wet (BLH habitat impacted by the construction of the WSLP Project would be mitigated in accordance with EA 576).

This Supplemental EIS would provide an assessment of proposed alternative projects to compensate for the WSLP Project's swamp impacts and it would identify the Tentatively Selected Alternative. When unavoidable impacts occur, the CEMVN is required to offset those impacts through compensatory mitigation by replacing the lost habitat's functions and services equally and in-kind. Compensatory mitigation is required by the Water Resources Development Act (WRDA) of 1986, Section 906, as amended, and by the Clean Water Act Section 404(b)(1) Guidelines. The MSP is a freshwater diversion that would reconnect the

Mississippi River to the Maurepas Swamp, strategically delivering nutrient-laden river water to restore a degraded Cypress-Tupelo swamp. The proposed diversion has a 2,000 cubic foot per second (cfs) design flow. The freshwater intake structure and conveyance channel are located on the east bank of the Mississippi River in St. John the Baptist Parish, immediately west of Garyville, Louisiana, at River Mile 144 Above Head of Passes. The construction corridor for the conveyance channel extends from LA 44 (River Road) northward for 5½ miles, terminating at the outfall structure, which is approximately 1,000 ft north of Interstate 10.

2. Scoping Process. The CEMVN invites all affected federal, state, and local agencies, affected Native American Tribes, other interested parties, and the general public to participate in the National Environmental Policy Act (NEPA) scoping process during development of the SEIS. The purpose of the public scoping process is to provide information to the public, narrow the scope of analysis to significant environmental issues, serve as a mechanism to solicit agency and public input on potential alternatives and issues of concern, and ensure full and open participation in scoping for the SEIS. CEMVN requests input from interested parties regarding potential WSLP mitigation alternatives and information and analyses relevant to the proposed MSP. To ensure that all the issues related to the proposed MSP are addressed, the CEMVN will conduct virtual and, if permissible, in-person public scoping meeting(s) to which agencies, organizations, and members of the general public are invited to present comments or suggestions with regard to the range of actions, alternatives, and potential impacts to be considered in the SEIS. Project and public scoping meeting information, including information as to where, when, and how to participate and submit scoping comments as well as other opportunities for public involvement, will be available on CEMVN's website at: *https://www.mvn.usace.army.mil/Missions/Environmental/NEPA-Compliance-Documents/Bipartisan-Budget-Act-2018-BBA-18/West-Shore-Lake-Pontchartrain/*.

Notification of public scoping meetings will also be available via press releases, special public notices, and on CEMVN's social media platforms.

3. Federal Authority. The SEIS will disclose the context and intensity of environmental impacts, including focusing the analysis on those effects that are reasonably foreseeable and that have a reasonably close causal relationship to the proposed action as required under the Council of Environmental Quality's (CEQ) NEPA regulations at 40 CFR parts 1500–1508 and the Department of the Army's NEPA regulations at 33 CFR part 230. A reasonable range of alternatives will be determined, and significant issues related to the proposed action will be identified during public scoping.

The following agencies are being invited to participate as Cooperating Agencies on the SEIS: United States Environmental Protection Agency; United States Department of the Interior, Fish and Wildlife Service (USFWS); United States Department of Commerce, National Marine Fisheries Service (NMFS); United States Department of Agriculture, Natural Resources Conservation Service; Advisory Council on Historic Preservation (ACHP); State of Louisiana, Historic Preservation Office (SHPO), State of Louisiana Department of Natural Resources (LDNR), State of Louisiana Department of Wildlife and Fisheries (LDWF), and State of Louisiana, Coastal Protection and Restoration Authority (CPRA).

4. Alternatives. The SEIS will address a reasonable range of alternatives based on the proposed Project's purpose and need. The SEIS will compare, at a minimum, the previously identified BBA Alternative for the WSLP Project in EA 576 to Alternative 1 (MSP–1: Public and Private Lands) and Alternative 2 (MSP–2: Public Land Only) by using the Alternatives Evaluation and Comparison (AEC) process. The results of the AEC process would be presented in the SEIS. The BBA Alternative would compensate for the WSLP Project impacts of 955 AAHU of CZ swamp. The MSP Alternative would compensate for WSLP Project impacts of approximately 1,010 AAHU of CZ swamp.

5. Potentially Significant Issues. The SEIS will analyze the potential impacts on the human and natural environment resulting from the Project. The scoping, public involvement, and interagency coordination processes will help identify and define the range of potential significant issues that will be considered. Important resources and issues to be evaluated in the SEIS could include, but are not limited to, the reasonably foreseeable effects on tidal wetlands and other waters of the U.S.; aquatic resources; commercial and recreational fisheries; wildlife resources; essential fish habitat; water quality; cultural resources; geology and soils; hydrology and hydraulics; air quality; marine mammals; threatened and endangered species and their critical habitats; navigation and navigable waters; induced flooding; employment and incomes; land use; property values; tax revenues; population and housing; community and regional growth; environmental justice; community cohesion; public services; recreation; transportation and traffic; utilities and community service systems.

6. Environmental Consultation and Review and Authorizations. The proposed action is being coordinated with a number of federal, state, regional, and local agencies. In accordance with relevant environmental laws and regulations, CEMVN will consult with the following agencies: USFWS under the Fish and Wildlife Coordination Act; USFWS and NMFS under the Endangered Species Act; NMFS under the Magnuson-Stevens Fishery Conservation and Management Act; LDNR for Coastal Zone Consistency determination concurrence; and LDEQ for Clean Water Act, Section 401 Water Quality Certification; and, the ACHP, Louisiana SHPO, and the appropriate Tribal Historic Preservation Officers under the National Historic Preservation Act using an integrated NHPA Section 106/NEPA EIS process.

7. Availability. The SEIS is presently scheduled to be available for public review and comment in October 2021. A Final SEIS is scheduled for release in January 2022. A decision regarding implementation of the MSP is expected in 2022. All comments received throughout the review process will become part of the project file for the proposed Project and will be subject to public release.

Edward E. Belk, Jr.,

Programs Director, Mississippi Valley Division, U.S. Army Corps of Engineers.

[FR Doc. 2021–17313 Filed 8–12–21; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Navy

Certificate of Alternate Compliance for Block IV VIRGINIA Class Submarines

AGENCY: Department of the Navy, DoD.

ACTION: Notice of issuance of Certificate of Alternate Compliance.

SUMMARY: The U.S. Navy hereby announces that a Certificate of Alternate Compliance has been issued for Block IV VIRGINIA Class Submarines. All Block IV VIRGINIA Class submarines are built to the same design. Due to the special construction and purpose of each submarine of this class, the Deputy Assistant Judge Advocate General

(DAJAG)(Admiralty and Maritime Law) has determined that each submarine of this class is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with the navigation lights provisions of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS) without interfering with its special function as a naval vessel. The intended effect of this notice is to warn mariners in waters where 72 COLREGS apply.

DATES: This Certificate of Alternate Compliance is effective August 13, 2021 and is applicable beginning August 6, 2021.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Darren E. Myers, JAGC, U.S. Navy, Admiralty Attorney, Office of the Judge Advocate General, Admiralty and Maritime Law Division (Code 11), 1322 Patterson Ave. SE, Suite 3000, Washington Navy Yard, DC 20374–5066, 202–685–5040, or *admiralty@navy.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose.

Executive Order 11964 of January 19, 1977 and 33 U.S.C. 1605 provide that the requirements of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as to the number, position, range, or arc of visibility of lights or shapes, as well as to the disposition and characteristics of sound-signaling appliances, shall not apply to a vessel or class of vessels of the Navy where the Secretary of the Navy shall find and certify that, by reason of special construction or purpose, it is not possible for such vessel(s) to comply fully with the provisions without interfering with the special function of the vessel(s). Notice of issuance of a Certificate of Alternate Compliance must be made in the **Federal Register**.

In accordance with 33 U.S.C. 1605, the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, hereby finds and certifies that all Block IV VIRGINIA Class submarines are vessels of special construction or purpose, and that, with respect to the position of the following navigational lights, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS without interfering with the special function of the vessel:

Annex I, Section 2(a)(i) pertaining to the height of the masthead light; Annex I, Section 2(f)(i) pertaining to the vertical position of the masthead light; Annex I, Section 2(k) pertaining to the height of the forward anchor light; Rule 30(a) and Rule 21(e) pertaining to the 360 degree arc of visibility of the forward and aft anchor lights; Annex I, Section 3(b) pertaining to the position of the sidelights; Rule 21(c) pertaining to the position and the arcs of visibility of the stern light.

The DAJAG (Admiralty and Maritime Law) further finds and certifies that these navigational lights are in closest possible compliance with the applicable provision of the 72 COLREGS.

Authority: 33 U.S.C. 1605(c), E.O. 11964.

Approved: August 10, 2021.

K.R. Callan,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2021–17338 Filed 8–12–21; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0123]

Agency Information Collection Activities; Comment Request; Student Assistance General Provisions—Subpart K—Cash Management

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before October 12, 2021.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2021–SCC–0123. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208C, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Assistance General Provisions—Subpart K—Cash Management.

OMB Control Number: 1845–0106.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments; Individuals and Households.

Total Estimated Number of Annual Responses: 2,503,922.

Total Estimated Number of Annual Burden Hours: 764,450.

Abstract: The Department of Education (the Department) amended the Student Assistance General Provisions regulations issued under the Higher Education Act of 1965, as amended (HEA), to implement the changes made to the Student Assistance General Provisions regulations—Subpart K—Cash Management § 668.164—Disbursing funds. These regulations are

intended to ensure students and parents have convenient access to their Title IV, HEA program funds, do not incur unreasonable and uncommon financial account fees on these title IV funds and are not led to believe that they must open a particular financial account to receive their Federal student aid. This request is for an extension of the information collection for the requirements that are contained in the regulations § 668.164—Disbursing funds. The regulations require that an institution that makes direct payments to a student or parent by electronic funds transfer (EFT) and that chooses to enter into an arrangement described in 668.164(e) or (f), including an institution that uses a third-party servicer to make those payments, must establish a selection process under which the student chooses one of several options for receiving those Title IV, HEA fund payments. There has been no change to the regulations.

Dated: August 10, 2021.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–17360 Filed 8–12–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

DOE/NSF High Energy Physics Advisory Panel

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of renewal.

SUMMARY: Pursuant to the Federal Advisory Committee Act, and Code of Federal Regulations, and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the DOE/NSF High Energy Physics Advisory Panel (HEPAP) has been renewed for a two-year period. The Committee will provide advice and recommendations to the Director, Office of Science (DOE), and the Assistant Director, Directorate for Mathematical and Physical Sciences (NSF), on scientific priorities within the field of basic high energy physics research. Additionally, the Secretary of Energy has determined that renewal of the HEPAP is essential to conduct business of the Department of Energy and the National Science Foundation and is in the public interest in connection with the performance of duties imposed upon the Department of Energy b law. The Committee will continue to operate in accordance with the provisions of the Federal Advisory Committee Act, adhering to the rules and regulations in implementation of that Act.

FOR FURTHER INFORMATION CONTACT: Dr. John Kogut at (301) 903–1298 or email: *john.kogut@science.doe.gov.*

Signing Authority

This document of the Department of Energy was signed on August 9, 2021, by Miles Fernandez, Acting Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 10, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–17328 Filed 8–12–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its ''Industrial Relations,'' OMB Control Number 1910–0600. The proposed collection covers major Department contractor Human Resource information necessary for contract management, administration, and cost control.

DATES: Comments regarding this collection must be received on or before September 13, 2021. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4718.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Alesia Harmon, Contractor Human Resource Specialist, Office of Acquisition and Management (MA–612), U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585–1615. Phone: (202) 287–1476; Email: at *Alesia.Gant@hq.doe.gov*.

Reporting requirements can be found at: *https://www.energy.gov/sites/prod/files/2021/02/f82/Special%20H%20Clause%20-%20EMPLOYEE%20COMPENSATION_PAY%20AND%20BENEFITS.pdf.*

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.:* 1910–0600;

(2) *Information Collection Request Title:* Industrial Relations;

(3) *Type of Request:* Renewal;

(4) *Purpose:* This information is required for management oversight of the Department of Energy's Facilities Management Contractors and to ensure that the programmatic and administrative management requirements of the contracts are managed efficiently and effectively;

(5) *Annual Estimated Number of Respondents:* 282;

(6) *Annual Estimated Number of Total Responses:* 282;

(7) *Annual Estimated Number of Burden Hours:* 3,529.5;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $0.

Statutory Authority: 42 U.S.C. 7256; 48 CFR 970.0370.1.

Signing Authority: This document of the Department of Energy was signed on July 19, 2021, by John R. Bashista, Director, Office of Acquisition Management, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this

document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 10, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–17364 Filed 8–12–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7186–052]

Missiquoi, LLC; Notice of Application for Amendment of License, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Proceeding:* Application for non-capacity amendment of license.

b. *Project No.:* 7186–052.

c. *Date Filed:* August 2, 2021.

d. *Licensee:* Missiquoi, LLC.

e. *Name of Project:* Sheldon Springs Hydroelectric Project.

f. *Location:* The project is located on the Missiquoi River in the Town of Sheldon in Franklin County, Vermont.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Licensee Contact:* Kevin Webb, Central Rivers Power MA, LLC, 670 N. Commercial Street, Suite 204, Manchester NH, 03101 (978) 935–6039 *kwebb@centralriverspower.com.*

i. *FERC Contact:* Rebecca Martin, (202) 502–6012, *Rebecca.martin@ferc.gov.*

j. *Deadline for filing comments, interventions, and protests Deadline for filing comments, motions to intervene, and protests:* September 8, 2021.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–7186–052. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The Licensee proposes to change the project's mode of operation from a peaking facility, with two feet of storage, to a run-of-river facility whereby inflow equals outflow year-round, with allowance for minor, short-term deviations for flashboard maintenance or for recreational purposes required under the project's current license. The project has already been operating as a run-of-river project for over 10 years.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: August 9, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–17383 Filed 8–12–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2354–151]

Georgia Power Company Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Application for variance from Article 418.

b. *Project No.:* 2354–151.

c. *Date Filed:* July 9, 2021.

d. *Applicant:* Georgia Power Company.

e. *Name of Project:* North Georgia Hydroelectric Project.

f. *Location:* Tugalo Park is located at the headwaters of Yonah Lake in Habersham County, Georgia.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Joseph Charles, (404) 782–8796, *jcharles@southernco.com.*

i. *FERC Contact:* Tara Perry, (202) 502–6546, *tara.perry@ferc.gov*.

j. *Deadline for filing comments, motions to intervene, and protests:* September 8, 2021.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2354–151. Comments emailed to Commission staff are not considered part of the Commission record.

k. *Description of Request:* The licensee requests a variance from Article 418 which requires, in part, the licensee to operate and maintain the Tugalo Park recreation site. As part of a hydro modernization program, the licensee is planning to replace several plant systems, including the turbines and generators, spillway gates, control system, and associated auxiliary equipment, at the Tugalo dam and powerhouse. Due to the rugged terrain and limited access in the area, the licensee would bring the heavy equipment and materials needed for the modernization work through the Yonah Lake and use the Tugalo Park area for construction staging. For safety and security reasons, the licensee is proposing to temporarily close the park to public access, starting October 1, 2021 for up to five years (October 2026). Following completion of the modernization work, the licensee would replace the existing recreation facilities (10 primitive campsites, restrooms, and a boat ramp). There are other nearby recreation sites and opportunities that would be available to the public during the time of the site closure.

l. *Locations of the Application:* In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''elibrary'' link. Enter the docket number excluding the last three digits in the document field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3673 or TYY, (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: August 9, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–17384 Filed 8–12–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC21–112–000.

Applicants: Puget Sound Energy, Inc., Macquarie Washington Clean Energy Investment, L.P., 2848926 Ontario Limited, CPP Investment Board (USRE II), Inc.

*Description:*Application for Authorization Under Section 203 of the Federal Power Act of Puget Sound Energy, Inc.

Filed Date: 8/9/21.

Accession Number: 20210809–5075.

Comment Date: 5 p.m. ET 8/30/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER19–62–004.

Applicants: OneEnergy Baker Point Solar, LLC.

Description: Compliance filing: Informational Filing Pursuant to Section 2 of the PJM OATT & Request for Waiver to be effective N/A.

Filed Date: 8/9/21.

Accession Number: 20210809–5011.

Comment Date: 5 p.m. ET 8/30/21.

Docket Numbers: ER21–1807–001.

Applicants: Hill Top Energy Center LLC.

Description: Compliance filing: Compliance Filing Under Docket Nos. ER21–1807 and EL21–81 to be effective 6/1/2021.

Filed Date: 8/9/21.

Accession Number: 20210809–5079.

Comment Date: 5 p.m. ET 8/30/21.

Docket Numbers: ER21–1993–002.

Applicants: Upper Missouri G. & T. Electric Cooperative, Inc.

Description: Tariff Amendment: Supplement to Response to Deficiency Letter (Revised Rate Schedules 1,5,7,8,9) to be effective 5/25/2021.

Filed Date: 8/6/21.

Accession Number: 20210806–5223.

Comment Date: 5 p.m. ET 8/27/21.

Docket Numbers: ER21–2625–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original ISA, Service Agreement No.

6119; Queue No. AE2–285 to be effective 7/14/2021.

Filed Date: 8/9/21.

Accession Number: 20210809–5062.

Comment Date: 5 p.m. ET 8/30/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 9, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–17333 Filed 8–12–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 539–015]

Lock 7 Hydro Partners, LLC; Notice of Intent To Prepare an Environmental Assessment

On April 30, 2020, Lock 7 Hydro Partners, LLC filed an application for a new major license for the 2.21-megawatt Mother Ann Lee Hydroelectric Station Water Power Project (Mother Ann Lee Project) (FERC No. 539). The Mother Ann Lee Project is located on the Kentucky River in Mercer, Jessamine, and Garrard Counties, Kentucky. The project does not occupy federal land.

In accordance with the Commission's regulations, on February 26, 2021, Commission staff issued a notice that the project was ready for environmental analysis (REA notice). Based on the information in the record, including comments filed on the REA notice, staff does not anticipate that licensing the project would constitute a major federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an Environmental Assessment (EA) on the application to license the Mother Ann Lee Project.

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA.	October 2021.[1]
Comments on EA	November 2021.

Any questions regarding this notice may be directed to Joshua Dub at (202) 502–8138 or *joshua.dub@ferc.gov.*

Dated: August 9, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–17382 Filed 8–12–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2021–0083; FRL–8793–01–OCSPP]

Pesticide Product Registration; Receipt of Applications for New Active Ingredients (July 2021)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before September 13, 2021.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the File Symbol of interest as shown in the body of this document, online at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets/about-epa-dockets.*

Due to the public health concerns related to COVID–19, the EPA/DC and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on the EPA/DC and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (BPPD) (7511P), main telephone number: (703) 305–7090, email address: *BPPDFRNotices@epa.gov;* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a

[1] The Council on Environmental Quality's (CEQ) regulations under 40 CFR 1501.10(b)(1) require that EAs be completed within 1 year of the federal action agency's decision to prepare an EA. This notice establishes the Commission's intent to prepare an EA for the Mother Ann Lee Project. Therefore, in accordance with CEQ's regulations, the EA must be issued within 1 year of the issuance date of this notice.

copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications. For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation website for additional information on this process (*http://www2.epa.gov/pesticide-registration/public-participation-process-registration-actions*).

Notice of Receipt—New Active Ingredients

1. File Symbol: 71771–RG. *Docket ID number:* EPA–HQ–OPP–2021–0394. *Applicant:* Plant Health Care Inc., 2626 Glenwood Ave., Suite 350, Raleigh, NC 27608. *Product name:* PHC 25279. *Active ingredient:* Biochemical Pesticide—PDHP 25279 at 1%. *Proposed use:* Fungicide. *Contact:* BPPD.

2. File Symbol: 91283–I. *Docket ID number:* EPA–HQ–OPP–2021–0421. *Applicant:* Amoéba SA, 38 Avenue de Frères Montgolfier, F–69680 Chassieu, France (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192). *Product name:* Makycin. *Active ingredient:* Fungicide—Lysate of *Willaertia magna* C2c Maky at 100%. *Proposed use:* Fungicide. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: August 10, 2021.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Program Support.

[FR Doc. 2021–17380 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2008–0707; FRL–8866–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Data Reporting Requirements for State and Local Vehicle Emission Inspection and Maintenance (I/M) Programs (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Data Reporting Requirements for State and Local Vehicle Emission Inspection and Maintenance (I/M) Programs (EPA ICR Number 1613.07, OMB Control Number 2060–0252) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through October 31, 2021. Public comments were previously requested via the **Federal Register** on March 1, 2021, which included a 60-day comment period ending on April 30, 2021. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before September 13, 2021.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2008–0707, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room has remained closed to public visitors since March 31, 2020, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov,* as there is a temporary suspension of mail delivery to EPA, and no hand deliveries are currently accepted. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Joe Winkelmann, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan 48105; telephone number: 734–214–4255; email address: *winkelmann.joseph@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov.* For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

Abstract: Clean Air Act section 182 and EPA's regulations (40 CFR part 51, subpart S) establish the requirements for state and local I/M programs that are included in state implementation plans (SIPs). To provide general oversight and support to these programs, EPA requires that state agencies with basic and enhanced I/M programs collect two varieties of reports for submission to the Agency:

- An annual report providing general program operating data and summary statistics, addressing the program's current design and coverage, a summary of testing data, enforcement program efforts, quality assurance and quality control efforts, and other miscellaneous information allowing for an assessment of the program's relative effectiveness; and
- A biennial report on any changes to the program over the two-year period and the impact of such changes, including any deficiencies discovered and corrections made or planned.

General program effectiveness is determined by the degree to which a program misses, meets, or exceeds the

emission reductions committed to in the state's approved SIP, which, in turn, must meet or exceed the minimum emission reductions expected from the relevant performance standard, as promulgated under 40 CFR part 51, subpart S, in response to requirements established in section 182 of the Clean Air Act. This information is used by EPA to determine a program's progress toward meeting requirements under 40 CFR part 51, subpart S, and to provide background information in support of program evaluations. Additional information regarding the current renewal of this ICR as well as previous renewals can be found in Docket ID No. EPA–HQ–OAR–2008–0707.

Form Numbers: None.

Respondents/affected entities: State governments.

Respondent's obligation to respond: Mandatory (40 CFR 51.366).

Estimated number of respondents: 26 (total).

Frequency of response: Annual and biennial.

Total estimated burden: 2,236 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $148,824 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in Estimates: There is a decrease of 172 hours in the total estimated respondent burden compared with the ICR currently approved by OMB due to a reduction in the number of respondents covered by the collection.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–17316 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R10–OAR–2020–0724; FRL–8863–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Federal Implementation Plans Under the Clean Air Act for Indian Reservations in Idaho, Oregon and Washington (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Federal Implementation Plans under the Clean Air Act for Indian Reservations in Idaho, Oregon and Washington (EPA ICR Number 2020.08, OMB Control Number 2060–0558), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through August 31, 2021. Public comments were previously requested via the **Federal Register** on February 12, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before September 13, 2021.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–R10–OAR–2020–0724, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sarah Frederick, Region 10 Air and Radiation Division, telephone number: (206) 553–1601; email address: *Frederick.Sarah@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: EPA promulgated Federal Implementation Plans (FIPs) under the Clean Air Act for Indian reservations located in Idaho, Oregon, and Washington in 40 CFR part 49 (70 FR 18074, April 8, 2005). The FIPs in the final rule, also referred to as the Federal Air Rules for Indian Reservations in Idaho, Oregon, and Washington (FARR), include information collection requirements associated with the partial delegation of administrative authority to a Tribe in 40 CFR 49.122; the rule for limiting visible emissions at 40 CFR 49.124; fugitive particulate matter rule in 40 CFR 49.126; the wood waste burner rule in 40 CFR 49.127; the rule for limiting sulfur in fuels in 40 CFR 49.130; the rule for open burning in 40 CFR 49.131; the rules for general open burning permits, agricultural burning permits, and forestry and silvicultural burning permits in 40 CFR 49.132, 49.133, and 49.134; the rule for emissions detrimental to human health and welfare in 40 CFR 49.135; the registration rule in 40 CFR 49.138; and the rule for non-title V operating permits in 40 CFR 49.139. EPA uses this information to manage the activities and sources of air pollution on the Indian reservations in Idaho, Oregon, and Washington. EPA believes these information collection requirements are appropriate because they will enable EPA to develop and maintain accurate records of air pollution sources and their emissions, track emissions trends and changes, identify potential air quality problems, allow EPA to issue permits or approvals, and ensure appropriate records are available to verify compliance with these FIPs. The information collection requirements listed above are all mandatory. Regulated entities can assert claims of business confidentiality and EPA will address these claims in accordance with the provisions of 40 CFR part 2, subpart B.

Form Numbers:

EPA Form 7630–1 Nez Perce Reservation Air Quality Permit: Agricultural Burn

EPA Form 7630–2 Nez Perce Reservation Air Quality Permit: Forestry Burn

EPA Form 7630–3 Nez Perce Reservation Air Quality Permit: Large Open Burn

EPA Form 7630–4 Initial or Annual Source Registration

EPA Form 7630–5 Report of Change of Ownership

EPA Form 7630–6 Report of Closure

EPA Form 7630–7 Report of Relocation
EPA Form 7630–8 Small Burn Air Quality Permit Application
EPA Form 7630–9 Non-Title V Operating Permit Application Form
EPA Form 7630–10 Umatilla Indian Reservation: Agricultural Burn Permit Application
EPA Form 7630–11 Umatilla Indian Reservation: Forestry Burn Permit Application
EPA Form 7630–12 Umatilla Indian Reservation: Large Open Burn Permit Application
EPA Form 5800–057 FARR Online Reporting System Initial or Annual Source Registration

Respondents/affected entities: Owners and operators of air emission sources in all industry groups and tribal governments, located in the identified Indian reservations.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 1,732 (total).

Frequency of response: Annual or occasional.

Total estimated burden: 3,601 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $286,888 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is decrease of 614 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is based on input from source consultations, supersedence of the provisions of one rule (49.139), and information we have learned about the source universe through implementing the rules since the ICR was updated in 2018.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–17315 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0628; FRL–8864–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Sulfuric Acid Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Sulfuric Acid Plants (EPA ICR Number 1057.15, OMB Control Number 2060–0041), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through October 31, 2021. Public comments were previously requested, via the **Federal Register**, on February 8, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before September 13, 2021.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2020–0628, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

The EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/,* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on the EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Owners and operators of sulfuric acid plants are required to comply with reporting and record keeping requirements for the General Provisions (40 CFR part 60, subpart A), as well as for the applicable specific standards in 40 CFR part 60 Subpart H. This includes submitting initial notifications, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by the EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Sulfuric acid manufacturing plants.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart H).

Estimated number of respondents: 53 (total).

Frequency of response: Semiannually.

Total estimated burden: 13,500 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,900,000 (per year), which includes $309,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is no increase in burden from the most-

recently approved ICR as currently identified in the OMB Inventory of Approved Burdens. This is due to several considerations: (1) The regulations have not changed over the past three years and are not anticipated to change over the next three years; and (2) the growth rate for this industry is very low or non-existent, so there is no significant change in the number of respondents. Since there are no changes in the regulatory requirements and there is no significant industry growth, there are also no changes in the capital/startup costs. Operation and maintenance (O&M) costs have been adjusted using the CEPCI Index to reflect the increase in costs since 2005.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–17314 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0623; FRL–8867–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Natural Gas Transmission and Storage (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Natural Gas Transmission and Storage (EPA ICR Number 1789.11, OMB Control Number 2060–0418), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through October 31, 2021. Public comments were previously requested, via the **Federal Register**, on February 8, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before September 13, 2021.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2020–0623, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/,* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on the EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Natural Gas Transmission and Storage (40 CFR part 63, subpart HHH) apply to existing facilities and new facilities that are major sources of hazardous air pollutants (HAP) and that either transport or store natural gas prior to entering the pipeline to a local distribution company or to a final end user (if there is no local distribution company). In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 63, subpart HHH.

Form Numbers: None.

Respondents/affected entities: Natural gas transmission and storage facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart HHH).

Estimated number of respondents: 73 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 3,780 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $448,000 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase in the total estimated burden from the most recently-approved ICR as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. This increase is due to an increase in the number of affected sources subject to the rule based on the latest available data and taking into account growth in this industry. The growth rate for the industry is based on our consultations with the Agency's internal industry experts, including a review of EPA's ECHO, GHGRP, and data from related rulemakings. There are no capital/startup or operation and maintenance costs incurred as a result of these standards because the industry has primarily installed flares to control emissions.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–17321 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0633; FRL–8865–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Polymeric Coating of Supporting Substrates Facilities (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Polymeric Coating of Supporting Substrates Facilities (EPA ICR Number 1284.12, OMB Control Number 2060–0181), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through October 31, 2021. Public comments were previously requested, via the **Federal Register**, on February 8, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before September 13, 2021.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2020–0633, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of polymeric coating of supporting substrates facilities are required to comply with reporting and record keeping requirements for the General Provisions of 40 CFR part 60, subpart A, as well as for the applicable specific standards in 40 CFR part 60 Subpart VVV. This includes submitting initial notifications, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Polymeric coating of supporting substrates facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart VVV).

Estimated number of respondents: 74 (total).

Frequency of response: Quarterly and semiannually.

Total estimated burden: 16,400 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $2,770,000 (per year), which includes $826,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an increase in burden from the most-recently approved ICR as currently identified in the OMB Inventory of Approved Burdens. This is due to an increase in the number of respondents subject to the rule. An examination of EPA's Enforcement and Compliance History Online (ECHO) database indicated that there are 72 sources currently reporting under NSPS Subpart VVV, an increase of 10 sources from the previous ICR. The regulations have not changed over the past three years and are not anticipated to change over the next three years. The increase in the operation and maintenance (O&M) costs is due to the increase in the number of respondents performing monitoring activities. The rate of increase in the number of new respondents remains steady at one new source per year, so the capital/startup cost will not increase.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–17318 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9057–8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed August 2, 2021 10 a.m. EST

Through August 9, 2021 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20210113, Final, USACE, CA, Adoption—Westside Subway Extension Transit Corridor Project Extension of the Existing Metro Purple Line and Metro Red Line Heavy Rail Subway Los Angeles County Metropolitan Transportation Authority Los Angeles County CA, Review Period Ends: 09/13/2021, Contact: Kathlyn Osagie 213–330–6030.

The U.S. Army Corps of Engineers (USACE) has adopted the Federal Transit Administration's Final EIS No. 20120072, filed 03/15/2012 with the Environmental Protection Agency. The USACE was not a cooperating agency on this project. Therefore, republication of the document is necessary under

Section 1506.3(c) of the CEQ regulations.

EIS No. 20210114, Final, NRC, TX, Interim Storage Partners LLC's License Application for a Consolidated Interim Storage Facility for Spent Nuclear Fuel in Andrews County, Texas, Review Period Ends: 09/13/2021, Contact: James R. Park 301–415–6954.

EIS No. 20210115, Final Supplement, USACE, CA, Adoption—Westside Purple Line Extension Section 4(f) Evaluation, Review Period Ends: 09/13/2021, Contact: Kathlyn Osagie 213–330–6030.

The U.S. Army Corps of Engineers (USACE) has adopted the Federal Transit Administration's Final Supplemental EIS No. 20170235, filed 11/24/2017 with the Environmental Protection Agency. The USACE was not a cooperating agency on this project. Therefore, republication of the document is necessary under Section 1506.3(c) of the CEQ regulations.

EIS No. 20210116, Draft, USFS, CO, Grand Mesa, Uncompahgre and Gunnison Forest Plan Revision, Comment Period Ends: 11/12/2021, Contact: Samantha Staley 970–852–9812.

Amended Notice

EIS No. 20210092, Draft, USAF, ID, Airspace Optimization for Readiness for Mountain Home Air Force Base, Comment Period Ends: 09/22/2021, Contact: Robin Divine 210–925–2730.

Revision to FR Notice Published 07/09/2021; Extending the Comment Period from 08/23/2021 to 09/22/2021.

Dated: August 9, 2021.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2021–17325 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2019–0675; FRL 5880–03–OW]

Ambient Water Quality Criteria To Address Nutrient Pollution in Lakes and Reservoirs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the release of *Ambient Water Quality Criteria to Address Nutrient Pollution in Lakes and Reservoirs.* These national recommended criteria are models for total nitrogen and total phosphorus concentrations in lakes and reservoirs to protect three different designated uses—aquatic life, recreation, and drinking water source protection—from the adverse effects of nutrient pollution. Nutrient pollution can degrade the conditions of water bodies worldwide, and the effects of excess nitrogen and phosphorus may be particularly evident in lakes and reservoirs. These recommended criteria are based on stressor-response models, which link nutrient pollution stressors (nitrogen, phosphorus) to responses associated with protection of designated uses. Models and associated criteria provided in this document are based on national data. States and authorized tribes can also incorporate local data, when available, into the national models, helping states and authorized tribes to derive numeric nutrient criteria that apply relationships estimated from national data while accounting for unique local conditions. These recommended criteria replace numeric nutrient criteria recommended by EPA in 2000 and 2001 for lakes and reservoirs for 12 out of 14 ecoregions of the conterminous United States. This document was released for 60-day public comment in the **Federal Register** on May 22, 2020. The comment period was extended 30 days, for a total comment period of 90 days. EPA has considered the comments, made minor revisions to the draft document in response, and published this final document to provide recommendations for states and authorized tribes interested in establishing water quality standards under the Clean Water Act (CWA) to protect the designated uses of their lakes and reservoirs from nutrient pollution.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2019–0675. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Lester Yuan, Health and Ecological Criteria Division, Office of Water (Mail Code 4304T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566–0908; email address: *yuan.lester@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What is nutrient pollution, and why is EPA concerned about it?

Nutrient pollution, or the excess loading of nitrogen and phosphorus, can degrade the conditions of water bodies and potentially make them unsafe for aquatic life, recreation, or to use as drinking water sources. Nutrient pollution stimulates excess growth of algae, which can limit the recreational use of lakes and reservoirs. Overabundant algae also increase the amount of organic matter in a lake or reservoir, which, when decomposed, can depress dissolved oxygen concentrations below levels needed to sustain aquatic life. In extreme cases, the depletion of dissolved oxygen causes fish kills. Nutrient pollution can also stimulate the excess growth of nuisance algae, such as cyanobacteria, which can produce cyanotoxins that are toxic to animals and humans. Elevated concentrations of these cyanotoxins can reduce the suitability of a lake or reservoir for recreation and as a source of drinking water.

II. Information on Recommended Ambient Water Quality Criteria for Lakes and Reservoirs

These recommended ambient water quality criteria for lakes and reservoirs are part of EPA's ongoing efforts to support states and authorized tribes in developing and adopting numeric nutrient criteria. Numeric nutrient criteria provide an important tool for managing the effects of nutrient pollution by providing nutrient goals that support the protection and maintenance of the designated uses of the waters of the United States. Recognizing the utility of such criteria, EPA published recommended numeric nutrient criteria for lakes and reservoirs for 12 out of 14 ecoregions of the conterminous United States from 2000 to 2001. These criteria were derived by analyzing available data on the concentrations of total nitrogen, total phosphorus, chlorophyll *a,* and Secchi depth. Scientific understanding of the relationships between nutrient concentrations and deleterious effects in lakes and reservoirs has increased since 2001, and standardized, high-quality data collected from lakes and reservoirs across the United States have become available. In this document, EPA describes analyses of these new data and provides models to derive numeric nutrient criteria for lakes and reservoirs

that replace the recommended numeric nutrient criteria of 2000 and 2001. These models and associated criteria are provided in accordance with the provisions of CWA Section 304(a) for EPA to revise national recommended ambient water quality criteria from time to time to reflect the latest scientific knowledge. The ecological responses on which these models and criteria are based were selected by applying a risk assessment approach to explicitly link nutrient concentrations to the protection of designated uses.

The recommended ambient water quality criteria for lakes and reservoirs are based on the available data from EPA's National Lakes Assessment (NLA) survey. The NLA surveys are carried out under EPA's National Aquatic Resource Survey program, which conducts water quality and biological surveys of the nation's surface waters in partnerships with state and authorized tribal water quality monitoring programs (*https://www.epa.gov/national-aquatic-resource-surveys*). The NLA surveys were designed using random sampling of lakes and reservoirs across the United States, and as a result, the collected data represent the characteristics of the full population of United States lakes and reservoirs. The NLA surveys were implemented using standardized field sampling and analytical methods, with internal oversight and independent quality control surveillance yielding data of high quality and statistical rigor.

The stressor-response models used in generating the recommended ambient water quality criteria are based on previously published EPA technical guidance (U.S. EPA 2010, *Using stressor-response relationships to derive numeric nutrient criteria,* Office of Water, U.S. Environmental Protection Agency, Washington, DC, EPA–820–S–10–001), as well as scientific peer-reviewed statistical and modeling techniques. Models provided in the recommended criteria document are based on national data, but states and authorized tribes may have additional data collected during routine monitoring. Incorporating these local data into the national models can refine and improve the precision of the stressor-response relationships on a site-specific basis. EPA stands ready to assist states and authorized tribes to add their data into the models through the Nutrient Scientific Technical Exchange Partnership & Support (N–STEPS) program. In the appendices of the criteria document, EPA describes case studies in which state monitoring data have been combined with national data, yielding models that can be used to derive numeric nutrient criteria that account for both unique local conditions and national, large-scale trends.

III. What are CWA Section 304(a) recommended water quality criteria?

CWA Section 304(a) water quality criteria are non-binding recommendations developed by EPA under authority of CWA Section 304(a) based on the latest scientific knowledge on the effects that pollutant concentrations have on aquatic species, recreation, and/or human health.

CWA Section 304(a)(1) directs EPA to develop, publish, and, from time to time, revise criteria for water quality accurately reflecting the latest scientific knowledge. Water quality criteria developed under CWA Section 304(a) are based on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. CWA Section 304(a) recommended criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

CWA Section 304(a) recommended criteria provide non-binding guidance to states and authorized tribes in adopting water quality standards that ultimately provide a basis for controlling discharges of pollutants. Under the CWA and its implementing regulations, states and authorized tribes are to adopt water quality criteria to protect designated uses (*e.g.,* aquatic life, recreational use). EPA's recommended water quality criteria are not regulations and do not constitute legally binding requirements. States and authorized tribes may adopt other scientifically defensible water quality criteria that differ from these recommendations. The CWA and its implementing regulations require that any new or revised water quality standards adopted by the states and authorized tribes be scientifically defensible and protective of the designated uses of the bodies of water. States and authorized tribes have the flexibility to do this by adopting criteria based on (1) EPA's recommended criteria, (2) EPA's criteria modified to reflect site-specific conditions, or (3) other scientifically defensible methods.

IV. Use of the Recommended Ambient Water Quality Criteria for Lakes and Reservoirs by States and Authorized Tribes

EPA is publishing the recommended ambient water quality criteria for lakes and reservoirs for consideration by states and authorized tribes as they adopt numeric nutrient criteria to protect aquatic life, recreation, and drinking water sources from nutrient pollution. States and authorized tribes could consider using the recommendations as an alternative to or as a supplement of other scientifically defensible approaches. States and authorized tribes may also modify the criteria to reflect site-specific conditions or establish criteria based on other scientifically defensible methods (40 CFR 131.11(b)). These updated CWA Section 304(a) recommended nutrient criteria for lakes do not, as a general matter, compel a state or authorized tribe to revise current EPA approved and adopted criteria, Total Maximum Daily Load nutrient load targets, or nitrogen or phosphorus numeric values established by other scientifically defensible methods. As part of its triennial review, if a state or authorized tribe uses its discretion to not adopt new or revised nutrient criteria based on these CWA Section 304(a) recommended criteria, then the state or authorized tribe shall provide an explanation when it submits the results of its triennial review (40 CFR 131.20(a)).

V. What changed between the draft and final criteria?

Changes in the final recommended criteria document, compared to the May 2020 draft posted for public comment, include technical revisions to the models limited to the parameter estimates for the zooplankton model, which were updated to reflect a slight change in how the model calculates seasonal mean biomasses of phytoplankton and zooplankton. Other changes include the addition of an appendix that provides an example workflow for identifying appropriately protective numeric nutrient criteria using the interactive tools, as well as minor editorial revisions that clarify or expand on existing text.

Radhika Fox,

Assistant Administrator.

[FR Doc. 2021–17357 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2021–0532; FRL–8836–01–OW]

Notification of Safe Drinking Water Act (SDWA) Section 1441 Application Submissions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; request for comments.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing receipt of Certifications of Need applications pursuant to the Safe Drinking Water Act (SDWA) Section 1441. Seven public water systems and three publicly owned treatment works submitted these applications. Each applicant cited receipt of notices of *force majeure* or unavailability of treatment chemical via normal procurement channels. The notices explained that a significant curtailment of deliveries of chlorine and derivative treatment chemicals from producers and from producers to repackagers would necessitate either a reduction in allocations of chlorine, sodium hypochlorite, or ferric chloride relative to the contractual agreements or an outright cancellation of the contracts. The applications further stated that after receiving the notices, each of these utilities tried to identify alternate treatment chemical suppliers with no success. EPA is providing an opportunity for written comments from the public on the SDWA Section 1441 applications, from chemical producers and repackagers that could supply the required chlorine, sodium hypochlorite, or ferric chloride to the applicants, and from any other interested parties.

DATES: Comments must be received on or before August 27, 2021.

ADDRESSES: You may send comments, identified by Docket ID Number EPA–HQ–OW–2021–0532, by any of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov (our preferred method). Follow the online instructions for submitting comments.

Mail: U.S. Environmental Protection Agency, EPA Docket Center, Water Docket, Environmental Protection Agency, Mail code: 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery/Courier (by scheduled appointment only): EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday through Friday (except federal holidays).

Instructions: All submissions received must include the Docket ID No. EPA–HQ–OW–2018–0532 for this action. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov,* as there may be delay in processing mail. Hand deliveries and couriers may be received by scheduled appointment only. For further information of EPA Docket Center Services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For information on SDWA Section 1441 applications contact Gabrielle Minton, Office of Ground Water and Drinking Water, Water Security Division, at (202) 564–8284 or email *minton.gabrielle@epa.gov.* For information on water utility disinfection products contact Steve Allgeier, Office of Ground Water and Drinking Water, Water Security Division, at (569) 513–7131 or email *allgeier.steve@epa.gov.* For more information, visit EPA's website at: *https://www.epa.gov/waterutilityresponse/watersectorsupplychainchemicalshortages.*

SUPPLEMENTARY INFORMATION:

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I. General Information

A. Does this action impose any requirements on Public Water Systems (PWSs) or Publicly Owned Treatment Works (POTWs)?

This action, when published, will not impose any requirements on utilities.

B. Public Participation

Submit your comments, identified by Docket ID No. EPA–HQ–OW–2021–0532, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section of this document. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

EPA is temporarily suspending its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center Staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* as there may be a delay in processing mail. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

EPA continues to carefully monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID–19.

C. What should I consider as I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

Explain your views as clearly as possible.

Describe any assumptions that you used.

Provide any technical information and/or data you used that support your views.

Provide full references for any peer reviewed publication you used that support your views.

Provide specific examples to illustrate your concerns.

Offer alternatives.

Make sure to submit your comments by the comment period deadline. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date,

and **Federal Register** citation related to your comments.

II. Purpose, Background, and Statutory Requirements of This Action

This section briefly summarizes the purpose of this action and the statutory requirements.

A. What is the purpose of this action?

The purpose of this action is to provide notification of the applications received under SDWA Section 1441.

EPA has received applications for Certifications of Need under SDWA Section 1441 authority, from the following public water systems and publicly owned treatment works: City of Oceanside—Mission Basin Groundwater Purification Facility (PWSID CA3710014, 12.5% sodium hypochlorite, 5,000 gallons delivered every 65 days); City of Oceanside—Weese Filtration Plant (PWSID CA3710014, 12.5% sodium hypochlorite, 5,000 gallons delivered every 5 days); City of Oceanside—San Luis Rey Water Reclamation Facility (POTW ID R9–2019–0166, 12.5% sodium hypochlorite, 5,000 gallons delivered every 10 days); Western Municipal Water District—Western Water Recycling Facility (POTW ID R9–2003–0113, 12.5% sodium hypochlorite, 5,000 gallons delivered every 10 days); Western Municipal Water District—Western Riverside County Regional Wastewater Authority (POTW CA8000216, 12.5% sodium hypochlorite, 5,000 gallons delivered every 3 days); City of Poway (PWSID CA3710015, 100% gaseous chlorine, 5 tons delivered every 21 days); Jordan Valley River Water Conservancy District (PWSID UT18027, 100% gaseous chlorine, 12 tons delivered every 7 days); Helix Water District (PWSID CA3710010, 100% gaseous chlorine, 12 tons delivered every 14 days); Niagara Falls Water Board Wastewater Treatment Plant (PWSID NY0026336, 12.5% sodium hypochlorite, 30,000 gallons delivered every day); and the City of Farmington Water and Wastewater Utility (PWSID NM–35–10224, 38%–42% ferric chloride, 5,000 gallons delivered every 55 days).

Submitted applications were reviewed by EPA for accuracy, completeness, and basis for need. After the comment period, EPA will issue or deny Certifications of Need. If issued, EPA will transmit the Certifications of Need to the U.S. Department of Commerce Undersecretary for Business and Industrial Security to implement the certification by issuing an order to contracted suppliers. The orders will require repackagers and/or suppliers to provide the fully contracted chlorine and other derivative treatment chemical allocations to the utilities listed in this **Federal Register** document. EPA requests comment on the application submittals as well as feedback from repackagers or suppliers who may be able to assist.

On June 30, 2021, EPA Administrator Regan issued a letter to the chemical sector encouraging chemical manufacturers and suppliers to prioritize drinking water and wastewater systems. EPA has been in frequent communication with representatives from the chemical sector, including specific chlorine producers and chlorine repackagers. While drinking water and wastewater disinfection accounts for less than 5% of chlorine consumed in the U.S., the water sector's use of this chemical is essential for protecting public health.

The applicants indicated that if their public water systems cannot obtain a sufficient and reliable supply of the required treatment chemical in the form used at that treatment facility, they would be compelled to issue boil water notices and Tier 1 public notifications or shut down the treatment system until the supply of the required treatment chemical is restored. If public water systems are forced to shut down, the communities served by the system would lack a safe drinking water supply, with significant consequences to public health and the local economy. Similarly, if publicly owned treatment works lack adequate chlorine or derivative chemical supplies, they would be unable to disinfect treated wastewater prior to discharge to surface waters, potentially leading to an increase in the concentration of pathogens in the surface water, which may be used by downstream drinking water utilities as a source of drinking water or by recreational users.

B. Background and Statutory Requirements

Pursuant to SDWA Section 1441, a PWS or POTW may submit an application to the EPA Administrator for a Certification of Need when the amount of a ''chemical or substance necessary to effectively treat water is not reasonably available'' or ''will not be so available when required.'' 42 U.S.C. 300j(a). Upon receipt of the application, EPA must publish a notice in the **Federal Register**, notify in writing all individuals who could be subject to an order based on the Certification of Need, and provide time for written comment. EPA may waive such requirements when the agency finds for good cause that a waiver is necessary to protect public health. *Id.* at (b)(2). Within 30 days after publishing the notice in the **Federal Register** or after receipt of the application if publication is waived, EPA will either issue or deny the Certification of Need. *Id.* at (b)(3). The EPA Administrator has delegated the authority to receive applications for Certifications of Need, issue such certifications, and take other actions under SDWA Section 1441 to the EPA Assistant Administrator for Water.

If EPA issues the Certification of Need, the agency will forward it to the U.S. Department of Commerce (Department) for implementation. 42 U.S.C. 300j(c)(1). Within seven days of EPA issuing the certification, the Department will issue an order requiring the manufacturers, producers, processors, distributors, or repackagers of the chemical or substance, identified in the amount and form in the Certification of Need, that the Department determines the supplies to be necessary and appropriate. *Id.* Persons or companies subject to the order will be given a reasonable opportunity to consult with the Department with respect to implementation of the order. *Id.*

Radhika Fox,

Assistant Administrator.

[FR Doc. 2021–17358 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8844–01–R5]

Great Lakes Advisory Board Notice for Virtual Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting for Great Lakes Advisory Board.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the Environmental Protection Agency (EPA) provides notice of a public meeting for the Great Lakes Advisory Board (GLAB). Pre-registration is required.

DATES: This virtual public meeting will be held on August 30th, 2021 from 1:00 p.m. to 4:00 p.m. Central Daylight Time and August 31st from 9:00 a.m. to 12:00 p.m. Central Daylight Time. Members of the public seeking to view the meeting must register by 3:00 p.m. Central Daylight Time on August 23rd, 2021. Members of the public seeking to make comments relevant to issues discussed at the virtual meeting must register and indicate a request to make oral and/or written public comments in advance of

the meeting. For information on how to register, please see [How do I participate in the meeting] below.

FOR FURTHER INFORMATION CONTACT: Edlynzia Barnes, Designated Federal Officer (DFO), at *Barnes.Edlynzia@epa.gov* or 312–886–6249.

SUPPLEMENTARY INFORMATION:

I. General Information

The GLAB is chartered in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix 2, as amended) and 41 CFR 102–3.50(d). The Advisory Board provides advice and recommendations on matters related to the Great Lakes Restoration Initiative. The Advisory Board also advises on domestic matters related to implementation of the Great Lakes Water Quality Agreement between the U.S. and Canada. The major objectives are to provide advice and recommendations on: Great Lakes protection and restoration activities; long-term goals, objectives, and priorities for Great Lakes protection and restoration; and other issues identified by the Great Lakes Interagency Task Force/Regional Working Group.

II. How do I participate in the remote public meeting?

A. Remote Meeting

This meeting will be conducted as a virtual meeting on August 30th, 2021 from 1:00 p.m. to 4:00 p.m. Central Daylight Time and August 31st from 9:00 a.m. to 12:00 p.m. Central Daylight Time. You must register by 3:00 p.m. Central Daylight Time on August 23rd, 2021 to receive information on how to participate. You may also submit written or oral comments for the committee by following the processes outlined below.

B. Registration

Individual registration is required for participation in this meeting. Information on registration for this meeting can be found at *https://event.capconcorp.com/form/view.php?id=127543.* When registering, please provide your name, email, organization, city, and state. Please also indicate whether you would like to provide oral and/or written comments during the meeting at the time of registration.

C. Procedures for Providing Public Comments

Oral Statements: In general, oral comments at this virtual conference will be limited to the Public Comments portion of the meeting agenda. Members of the public may provide oral comments limited to up to three minutes per individual or group and may submit further information as written comments. Persons interested in providing oral statements should register at *https://event.capconcorp.com/form/view.php?id=127543* for the meeting and indicate your interest to provide public comments. Oral commenters will be provided an opportunity to speak in the order in which their request was received by the DFO and to the extent permitted by the number of comments and the scheduled length of the meeting. Persons not able to provide oral comments during the meeting will be given an opportunity to provide written comments after the meeting.

Written Statements: Persons interested in providing written statements pertaining to this committee meeting may do so by indicating at *https://event.capconcorp.com/form/view.php?id=127543.* Written comments will be accepted before, during, and after the public meeting and will be considered by the Great Lakes Advisory Board members.

D. Availability of Meeting Materials

The meeting agenda and other materials for the virtual conference will be posted on the GLAB website at *www.glri.us/glab.*

E. Accessibility

Persons with disabilities who wish to request reasonable accommodations to participate in this event may contact the DFO at *Barnes.edlynzia@epa.gov* or 312–886–6249 by 3:00 p.m. Central Daylight Time on August 23rd, 2021. All final meeting materials will be posted to the GLAB website in an accessible format following the meeting, as well as a written summary of this meeting.

Cheryl Newton,

Acting Regional Administrator, Great Lakes National Program Manager.

[FR Doc. 2021–17326 Filed 8–12–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1031; FR ID 42506]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before October 12, 2021. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1031.

Title: Commission's Initiative to Implement Enhanced 911 (E911) Emergency Services.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, and State, Local and Tribal government.

Number of Respondents and Responses: 22 respondents; 23 responses.

Estimated Time per Response: 2–4 hours.

Frequency of Response: On occasion, one-time reporting requirement, third party disclosure requirement, and recordkeeping requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. 154, 160, 201, 251–254, 303, and 332 of the Communications Act of 1934, as amended.

Total Annual Burden: 70 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No Impact(s).

Nature and Extent of Confidentiality: Respondents are not required to submit proprietary trade secrets or other confidential information. However, if a carrier believes the only way to satisfy the requirement for information is to submit what it considers to be proprietary trade secrets or other confidential information, the carrier may request that materials or information submitted to the Commission be withheld from public inspection and from the E911 website (see Section 0.459 of the Commission's rules).

Needs and Uses: The Commission is seeking an extension of this information collection from the Office of Management and Budget (OMB) for the three-year approval. The information collection requirements contained in this collection guarantee continued cooperation between wireless carriers and Public Safety Answering Points (PSAPs) in complying with the Commission's E911 requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–17365 Filed 8–12–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[ET Docket No. 20–36; Report No. 3178; FRS 42281]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for Reconsideration; correction.

SUMMARY: The Federal Communications Commission (Commission) published a document in the **Federal Register** of July 23, 2021 (86 FR 38969), regarding a Petition for Reconsideration filed in the Commission's rulemaking proceeding. In this document, the Commission corrects the dates for replies to an opposition.

DATES: Oppositions to the Petitions must be filed on or before August 9, 2021. Replies to an opposition must be filed on or before August 19, 2021.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Hugh VanTuyl, Office of Engineering and Technology, (202) 418–7506 or *Hugh.VanTuyl@fcc.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 21–15641, appearing on page 38969 in the **Federal Register** on July 23, 2021, the following correction is made:

DATES: [Corrected]

On page 38969, in the third column, the dates are corrected to read ''Oppositions to the Petitions must be filed on or before August 9, 2021. Replies to an opposition must be filed on or before August 19, 2021.''

Dated: August 4, 2021.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021–17282 Filed 8–12–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0807; FR ID 42526]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before October 12, 2021. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0807.

Title: Section 51.803, Procedures for Commission Notification of a State Commission's Failure to Act; Supplemental Procedures for Petitions Pursuant to Section 252(e)(5) of the Communications Act of 1934, as amended.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities and State, Local or Tribal government.

Number of Respondents and Responses: 60 respondents; 60 responses.

Estimated Time per Response: 40 hours per requirement.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 252(e)(5) as amended by the Communications Act of 1934, as amended.

Total Annual Burden: 1,600 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission is not requesting petitioners to submit confidential information to the Commission.

Needs and Uses: Any interested party seeking preemption of a state commission's jurisdiction based on the

state commission's failure to act shall notify the Commission as follows: (1) File with the Secretary of the Commission a detailed petition, supported by an affidavit, that states with specificity the basis for any claim that it has failed to act; and (2) serve the state commission and other parties to the proceeding on the same day that the party serves the petition on the Commission. Within 15 days of filing the petition, the state commission and parties to the proceeding may file a response to the petition. In an OMB-approved Public Notice, DA 97–2540, released December 4, 1997, the Commission set forth procedures for filing petitions for preemption pursuant to section 252(e)(5). Section 252(e)(5) provides that ''if a state commission fails to act to carry out its responsibility under this section in any proceeding or other matter under this section, then the Commission shall issue an order preempting the state commission's jurisdiction of the proceeding or matter within 90 days after being notified (or taking notice) of such failure, and shall assume the responsibility of the state commission under this section with respect to the proceeding or matter and act for the state commission.'' All of the requirements are used to ensure that petitioners have complied with their obligations under the Communications Act of 1934, as amended.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–17369 Filed 8–12–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm*. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than September 13, 2021.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *N.B.C. Bancshares in Pawhuska, Inc., Pawhuska, Oklahoma;* to acquire The American Bank, Wagoner, Oklahoma.

B. Federal Reserve Bank of San Francisco (Sebastian Astrada, Director, Applications) 101 Market Street, San Francisco, California 94105–1579:

1. *TriCo Bancshares, Chico, California;* to acquire Valley Republic Bancorp, and thereby indirectly acquire Valley Republic Bank, both of Bakersfield, California.

Board of Governors of the Federal Reserve System, August 10, 2021.

Ann Misback,

Secretary of the Board.

[FR Doc. 2021–17391 Filed 8–12–21; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm*. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 30, 2021.

A. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Security State Bank & Trust, Fredericksburg, Texas, as co-trustee of the Kathleen Keller 2016 Trust, Blanco County, Texas, and of the Kay Durst Family 2016 Trust, Gillespie County, Texas;* to retain voting shares of Security Holding Company, and thereby indirectly retain voting shares of Security State Bank & Trust, both of Fredericksburg, Texas.

Additionally, the Elliott Gage Hayne GST Trust, Elliott Gage Hayne, as trustee, the James L. Hayne, Jr. GST Trust, James L. Hayne, Jr., as trustee, the Nancy Elliott Hayne GST Trust, Nancy Elliott Hayne, as trustee, and the Walter Catto Hayne GST Trust, Walter Catto Hayne, as trustee, all of San Antonio, Texas; to join the Bonnen/Durst/Hayne/Igler/Keller/Kemp/LeJeune/Loth control group, a group acting in concert, to retain voting shares of Security Holding Company, and thereby indirectly retain voting shares of Security State Bank & Trust.

Board of Governors of the Federal Reserve System, August 10, 2021.

Ann Misback,

Secretary of the Board.

[FR Doc. 2021–17390 Filed 8–12–21; 8:45 am]

BILLING CODE P

OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities; Information Collection Renewal; Comment Request for OGE Form 278e Executive Branch Personnel Public Financial Disclosure Report

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice and request for comments.

SUMMARY: After publication of this second round notice, the Office of Government Ethics (OGE) intends to

request that the Office of Management and Budget (OMB) renew its approval under the Paperwork Reduction Act for an existing information collection, entitled the OGE Form 278e Executive Branch Personnel Public Financial Disclosure Report.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Grant Anderson at the U.S. Office of Government Ethics; telephone: 202–482–9318; TTY: 800–877–8339; Email: *Grant.Anderson@oge.gov.*

SUPPLEMENTARY INFORMATION:

Title: Executive Branch Personnel Public Financial Disclosure Report.

Agency Form Number: OGE Form 278e.

Abstract: The OGE Form 278 collects information from certain officers and high-level employees in the executive branch for conflicts of interest review and public disclosure. The form is also completed by individuals who are nominated by the President for high-level executive branch positions requiring Senate confirmation and individuals entering into and departing from other public reporting positions in the executive branch. The financial information collected relates to: Assets and income; transactions; gifts, reimbursements and travel expenses; liabilities; agreements or arrangements; outside positions; and compensation over $5,000 paid by a source—all subject to various reporting thresholds and exclusions. The information is collected in accordance with section 102 of the Ethics in Government Act, 5 U.S.C. app. sec. 102, as amended by the Representative Louise McIntosh Slaughter Stop Trading on Congressional Knowledge Act (Pub. L. 112–105) (STOCK Act) and OGE's implementing financial disclosure regulations at 5 CFR part 2634.

In 2013, OGE sought and received approval for the OGE Form 278e, an electronic version of the Form 278, implemented pursuant to the e-filing system mandated under section 11(b) of the STOCK Act. The OGE Form 278e collects the same information as the OGE Form 278. In 2014, OGE sought and received approval to incorporate the OGE Form 278e into its *Integrity* e-filing application. *Integrity* has been in use since January 1, 2015, and OGE now requires filers to use a version of the OGE Form 278e rather than the old OGE Form 278. The version of the Form 278e that is produced by *Integrity* is a streamlined output report format that presents only the filer's inputs in given categories and does not report other categories not selected by the filer. OGE also continues to maintain an Excel version of the form and a 508 compliant PDF version on its website.

A **Federal Register** Notice with a 60-day comment period soliciting comments on this information collection was published on June 2, 2021 (86 FR 29583). OGE received four responses to that notice, two of which contained several suggestions.

Several of the suggestions addressed the reporting requirements, for example eliminating the requirement to report diversified mutual funds. The financial disclosure requirements are dictated by the Ethics in Government Act (EIGA), 5 U.S.C. app. sec. 102, as amended. Therefore, these suggested changes could not be made without revisions to the EIGA. Several of the suggestions proposed user experience changes to the *Integrity* system. There is a pre-existing process to collect, analyze, and prioritize proposed changes to the *Integrity* system through the *Integrity* Advisory Council (IAC). Agency employees should forward suggestions concerning *Integrity* to their agency's *Integrity* administrator or an agency ethics official who can present the suggestions for IAC consideration.

Two suggestions involved the clarity of the form's instructions. One of these suggestions was considered, but it was determined that making the change would actually decrease the overall clarity of the instructions. The other suggestion made a valid point that a particular instruction can be confusing to filers, but offered no specific alternative. Without a specific alternative to consider, OGE is unable to make this change as part of the Paperwork Reduction Act renewal process. OGE intends to study the issue for a future revision.

Finally, several suggestions made by Citizens for Responsibility & Ethics in Washington (CREW) focused on requiring additional personal information from filers, which would increase the burden of the information collection and may implicate privacy concerns. One CREW proposal suggested requiring more information about filers' assets. That idea was previously considered and OGE determined that the resulting burden to the filer would be too high. Some of CREW's suggestions are not directly related to the purpose of the form and/or would require a legislative or regulatory change. To the extent that the proposed changes may assist the government in identifying potential conflicts of interest, they will be considered for a future iteration of the form.

OMB Control Number: 3209–0001.

Type of Information Collection: Extension of a currently approved collection.

Type of Review Request: Regular.

Affected Public: Private citizen Presidential nominees to executive branch positions subject to Senate confirmation; other private citizens who are potential (incoming) Federal employees whose positions are designated for public disclosure filing; those who file termination reports from such positions after their Government service ends; and Presidential and Vice-Presidential candidates.

Estimated Annual Number of Respondents: 3,196.

Estimated Time per Response: 10 hours.

Estimated Total Annual Burden: 31,960 hours.

Request for Comments: OGE is publishing this second round notice of its intent to request paperwork clearance renewal for OGE Form 278e. Public comment is invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). The comments will become a matter of public record.

Approved: August 10, 2021.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2021–17330 Filed 8–12–21; 8:45 am]

BILLING CODE 6345–03–P

OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities; Information Collection Renewal; Comment Request for OGE Form 450 Executive Branch Confidential Financial Disclosure Report

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice and request for comments.

SUMMARY: After publication of this second round notice, the Office of Government Ethics (OGE) plans to request that the Office of Management and Budget (OMB) renew its approval

under the Paperwork Reduction Act for an existing information collection, entitled the OGE Form 450 Executive Branch Confidential Financial Disclosure Report.

Comments: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Grant Anderson at the U.S. Office of Government Ethics; telephone: 202–482–9318; TTY: 800–877–8339; Email: *Grant.Anderson@oge.gov.*

SUPPLEMENTARY INFORMATION:

Title: Executive Branch Confidential Financial Disclosure Report.

Agency Form Number: OGE Form 450.

Abstract: The OGE Form 450 collects information from covered department and agency employees as required under OGE's executive branch wide regulatory provisions in subpart I of 5 CFR part 2634. The basis for the OGE reporting regulation is section 201(d) of Executive Order 12674 of April 12, 1989 (as modified by Executive Order 12731 of October 17, 1990) and section 107(a) of the Ethics in Government Act, 5 U.S.C. app. sec. 107(a). OGE maintains the form in three formats on its website: A PDF version, a 508 compliant PDF version, and an Excel spreadsheet version. OGE seeks renewal of the OGE Form 450 without modification.

A **Federal Register** Notice with a 60-day comment period soliciting comments on this information collection was published on June 2, 2021 (86 FR 29584). OGE received five responses to that notice, one of which did not directly address the information collection.

The other four comments suggest requiring additional information, apparently for the benefit of the government employees tasked with reviewing the information. These suggestions would add additional reporting burden to filers and could have privacy implications. One of the suggestions would also require a regulatory change. Accordingly, OGE declined to adopt these suggestions in seeking Paperwork Reduction Act renewal for the OGE Form 450.

OMB Control Number: 3209–0006.

Type of Information Collection: Extension of a currently approved collection.

Type of Review Request: Regular.

Affected public: Prospective Government employees, including special Government employees, whose positions are designated for confidential disclosure filing and whose agencies require that they file new entrant confidential disclosure reports prior to assuming Government responsibilities.

Estimated Annual Number of Respondents: 30,449.

Estimated Time per Response: 3 hours.

Estimated Total Annual Burden: 91,347 hours.

Request for Comments: OGE is publishing this second round notice of its intent to request paperwork clearance renewal for the OGE Form 450. Public comment is invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). The comments will become a matter of public record.

Approved: August 10, 2021.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2021–17331 Filed 8–12–21; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day–21–0048; Docket No. ATSDR–2021–0007]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ATSDR Exposure Investigations (EIs). The information collection is designed to evaluate public health issues at a site resulting from environmental exposure. ATSDR EIs fill data gaps by conducting environmental and biological sampling.

DATES: ATSDR must receive written comments on or before October 12, 2021.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2021–0007 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7118; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

ATSDR Exposure Investigations (EIs) (OMB Control No. 0923–0048, Exp. 04/30/2022)—Extension—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year extension of this generic clearance to allow the agency to conduct exposure investigations (EIs), through methods developed by ATSDR. After a chemical release or suspected release into the environment, EIs are usually requested by officials of a state health agency, county health department, the Environmental Protection Agency (EPA), the general public, and/or ATSDR staff. EI results are used by public health professionals, environmental risk managers, and other decision makers to determine if current conditions warrant intervention strategies to minimize or eliminate human exposure.

All of ATSDR's targeted biological assessments (*e.g.,* urine, blood) and some of the environmental investigations (*e.g.,* air, water, soil, dust, or food sampling) involve participants to determine whether they are or have been exposed to unusual levels of pollutants at specific locations (*e.g.,* where people live, spend leisure time, or anywhere they might come into contact with contaminants under investigation).

Questionnaires, appropriate to the specific contaminant, are generally needed in about half of the EIs (at most, approximately 12 per year) to assist in interpreting the biological or environmental sampling results. ATSDR collects contact information (*e.g.,* name, address, phone number) to provide the participant with their individual results. ATSDR also collects information on other possible confounding sources of chemical(s) exposure such as medicines taken, foods eaten, hobbies, jobs, etc. In addition, ATSDR asks questions on recreational or occupational activities that could increase a participant's exposure potential. The information collected represents an individual's exposure history.

The number of questions can vary depending on the number of chemicals being investigated, the route of exposure (*e.g.,* breathing, eating, touching), and the number of other sources of the chemical(s) (*e.g.,* products used, jobs). We use approximately 12–20 questions about the pertinent environmental exposures per investigation. A question bank is available for health assessors to use as a basis of questions to be asked during the EI, but EI-specific questions may be included as appropriate.

Typically, the number of participants in an individual EI ranges from 10 to 100. Participation is completely voluntary, and there are no costs to participants other than their time. Based on a maximum of 12 EIs per year and 100 participants each, the estimated annualized burden hours are 600.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr.)	Total Burden (in hr.)
Exposure Investigation Participants ..	Chemical Exposure Questions	1,200	1	30/60	600
Total	.....	.....	.....	.....	600

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–17351 Filed 8–12–21; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0083; NIOSH 278]

Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following virtual meeting of the Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH).

DATES: The meeting will be held on October 5, 2021, from 10:00 a.m.–3:30 p.m., EDT.

Written comments are due by September 28, 2021.

ADDRESSES: This is a virtual meeting. You may submit comments, identified by Docket No. CDC–2021–0083; NIOSH–278 by mail. CDC does not accept comments by email.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket number CDC–2021–0083; NIOSH–278, c/o Sherri Diana, NIOSH Docket Office, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226.

Instructions: All submissions received must include the Agency name and Docket Number. Written public comments received by September 28, 2021 will be provided to the BSC prior to the meeting. Docket number CDC–2021–0083; NIOSH–278 will close September 28, 2021.

FOR FURTHER INFORMATION CONTACT: Emily J.K. Novicki, M.A., M.P.H., Executive Secretary, BSC, NIOSH, CDC, 1600 Clifton Road NE, MS V24–4, Atlanta, GA 30329–4027, Telephone (404) 498–2581, or email at *enovicki@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly

or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors provides guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board provides guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board evaluates the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters To Be Considered: The agenda for the meeting addresses progress on the NIOSH Evaluation Capacity Building Plan; mental health initiative for health workers; and National Firefighter Registry. An agenda is also posted on the NIOSH website (*http://www.cdc.gov/niosh/bsc/*). Agenda items are subject to change as priorities dictate. Meeting Information: It is open to the public, limited only by web conference lines (500 web conference lines are available). Register at the NIOSH website *http://www.cdc.gov/niosh/bsc/* or call (404–498–2581) no later than September 28, 2021. Time will be available for public comment.

Public Participation

Comments received are part of the public record and are subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket. CDC does not accept comment by email.

Oral Public Comment: The public is welcome to participate during the public comment period, from 1:00 p.m. to 1:15 p.m., EDT, September 28, 2021. Please note that the public comment period ends at the time indicated above. Each commenter will be provided up to five minutes for comment. A limited number of time slots are available and will be assigned on a first come-first served basis. Members of the public who wish to address the NIOSH BSC are requested to contact the Executive Secretary for scheduling purposes (see **FOR FURTHER INFORMATION** above).

Written Public Comment: Written comments will also be accepted from those unable to attend the public session per the instructions provided in the address section above. Written comments received in advance of the meeting will be included in the official record of the meeting. Written comments received by September 28, 2021 will be provided to the BSC prior to the meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–17395 Filed 8–12–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–21–21HD; Docket No. CDC–2021–0080]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled One Health SARS–CoV–2 Animal Testing Form, which aims to improve the scientific community's understanding of the number of animals state officials report are tested for SARS–CoV–2, including the associated epidemiological data and testing results.

DATES: CDC must receive written comments on or before October 12, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0080 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

One Health SARS–CoV–2 Animal Testing Form—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The goal of this project is to collect information from state, tribal, local, and territorial partners on the scope and context of SARS–CoV–2 testing in animals in order to understand and monitor testing burden and prevalence of the virus among animal populations. Currently, most animal samples that test positive for SARS–CoV–2 are confirmed by the United States Department of Agriculture (USDA) National Veterinary Services Lab (NVSL), and are reported to the World Organization for Animal Health (OIE). However, no reporting requirements or mechanisms are in place to determine the number of negative results, total number of samples tested, and samples for which testing was not approved by state, territorial, local, or tribal health authorities. Additional information on the overall number of animals tested for SARS–CoV–2 will allow us to refine our understanding of the clinical course and presentation in animals, gain a sense of the burden that SARS–COV–2 testing places on health officials, and develop an estimate of national prevalence of SARS–CoV–2. In turn, these data can help inform guidance and recommendations, as well as surveillance directives for future emerging infectious diseases.

The need for these data has been discussed with federal, state, tribal, local, and territorial partners and the questionnaire was developed in consultation with these stakeholders. CDC requests approval for an estimated 8,000 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State public health veterinarians, State animal health officials, and wildlife veterinarians.	State Level Veterinary Authority Surveillance Questionnaire.	80	400	15/60	8,000

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–17348 Filed 8–12–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–21–0852; Docket No. CDC–2021–0082]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in U.S. Acute Care Hospitals. This project examines the numbers and types of Healthcare-Associated Infections and causative pathogens, types of antimicrobial drugs (such as antibiotics) used, and the quality of antimicrobial prescribing in U.S. acute care hospitals.

DATES: CDC must receive written comments on or before October 12, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0082 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in U.S. Acute Care Hospitals (OMB Control No. 0920–0852, Exp. 10/31/2022)—Extension—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Preventing healthcare-associated infections (HAIs) and improving antimicrobial use (AU) are both CDC and national priorities. An essential step in reducing the occurrence of HAIs is to accurately estimate the burden of these infections in U.S. acute care hospitals and to describe the types of HAIs and causative pathogens. Periodic assessments of the magnitude and types of HAIs and AU occurring in all patient populations within acute care hospitals are needed to inform decisions by policy makers and hospital infection control personnel (ICP) regarding appropriate targets and strategies for HAI prevention and antimicrobial stewardship.

Since 2009, CDC has conducted four prevalence surveys (*i.e.,* pilot survey in 2009, limited-scale survey in 2010, and two full-scale surveys in 2011 and 2015) in partnership with the CDC's Emerging Infections Program (EIP) sites. Findings from the most recent survey showed a reduction in the percentage of patients with healthcare-associated infections compared with 2011. CDC was granted approval from OMB to conduct a fifth survey in 2020, but due to the COVID–19 pandemic the survey was postponed to 2023.

Minor adjustments to data collection instruments since the previous 2019 OMB approval have been made. These adjustments were made to enhance future analyses and utility of the survey data. These changes are non-substantive and are not expected to increase the public reporting burden. An extension of the prevalence survey's existing OMB approval is sought to allow a repeat HAI and AU Prevalence Survey to be performed in 2023. A repeat survey will allow assessment of changes in HAI and AU prevalence, pathogen distribution, and quality of antimicrobial prescribing. These data will also allow CDC and its partners to continue to monitor HAI and AU trends, to measure progress in meeting national targets, and to further refine prevention strategies. In the 2023 survey, data collection will occur within acute care general hospitals of varying size in each of the 10 EIP sites (*i.e.,* CA, CO, CT, GA, MD, MN, NM, NY, OR, & TN).

Infection Control Personnel (ICP) in participating hospitals may assist EIP site personnel in collecting demographic and limited clinical data from the electronic or paper-based medical records of a sample of randomly selected patients on a single day in 2023. Patients will not be interviewed, and no direct interaction with patients will occur. Hospital and patient-level data will be collected using unique identification codes. EIP site personnel will submit hospital and patient-level data to CDC using a secure data management system.

Based on experiences from previous surveys, the time required to complete the Healthcare Facility Assessment Form (HFA) and Patient Information Form (PIF) is estimated to be 45 and 17 minutes, respectively. To conduct the full-scale survey in a three-year approval period, 100 hospital respondents will complete both the HFA (1x) and the PIF (on average 63x) per year.

To assess changes in HAIs and AU over time, EIP sites will seek participation from the same hospitals that participated in prior surveys. These hospitals were originally selected for participation using a stratified random sampling scheme based on the number of staffed acute care beds (*i.e.,* small: <150 staffed beds; medium: 151–399 staffed beds; large: >400 staffed beds). Each site will also have the option to recruit additional hospitals for a total of up to 30 in each site. As in previous surveys, hospital participation will remain voluntary. Within each participating hospital, EIP site personnel will establish patient sample size targets based on the number of staffed acute care beds (*e.g.,* up to 75 patients in small hospitals, 75 patients in medium hospitals, and 100 patients in large hospitals).

The total estimated annualized public burden is 1,860 hours, which represents no change from the 2019 OMB approval. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Hospital Staff (*i.e.,* Infection Preventionist).	Healthcare Facility Assessment	100	1	45/60	75
	Patient Information Form	100	63	17/60	1,785
Total					1,860

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–17353 Filed 8–12–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–21–0792]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Environmental Health Specialists Network (EHS-Net) Program'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on April 5, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Environmental Health Specialists Network (EHS-Net) Program (OMB Control No. 0920–0792, Exp. 8/31/2021)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting a three-year Paperwork Reduction Act (PRA) clearance for this generic clearance. This Revision information collection request (ICR) will allow the Environmental Health Specialists Network (EHS-Net) to collect research data focused on identifying and addressing the environmental causes of foodborne illness.

An estimated 47.8 million foodborne illnesses occur annually in the United States, resulting in 127,839 hospitalizations, and 3,037 deaths annually. These figures indicate that foodborne illness is a significant problem in the U.S. Reducing foodborne illness requires identification and understanding of the environmental factors that cause these illnesses, and it needs to be understood how and why food becomes contaminated with foodborne illness pathogens. This information can then be used to determine effective food safety prevention methods, increase regulatory program effectiveness, and decrease foodborne illness. The purpose of this food safety research program is to identify and understand environmental factors associated with foodborne illness and outbreaks. This program is conducted by the EHS-Net, a collaborative project of CDC, FDA, USDA, and local and state sites.

Environmental factors associated with foodborne illness include both food safety practices (*e.g.,* inadequate cleaning practices) and the factors in the environment associated with those practices (*e.g.,* worker and retail food establishment characteristics). To understand these factors, we need to collect data from those who prepare food (*i.e.,* food workers) and on the environments in which the food is prepared (*i.e.,* retail food establishment kitchens). Thus, data collection methods for this generic package include: (1) Manager and worker interviews/information collection instruments, and (2) observation of kitchen environments. Both methods allow data collection on food safety practices and environmental factors associated with those practices. To date, EHS-Net has conducted five studies under this generic clearance. The data from these studies have been disseminated to environmental public health/food safety regulatory programs and the food industry in the form of presentations at conferences and meetings, scientific journal publications, and website postings.

The current package differs from the previous package in three primary ways, described below.

- The sites in which data will be collected differ. CDC funded a renewal of the EHS-Net cooperative agreement in 2020; as a result, one site was dropped from the agreement (California), and one was added (Franklin County, Ohio). The other sites remained the same. These are: Harris County, Texas; Minnesota; New York; New York City, New York; Rhode Island; Southern Nevada Health District, Nevada; and Tennessee.
- Since the previous PRA clearance, the National Center for Environmental Health (NCEH) Human Subjects Coordinator has determined that EHS-Net information collections are not human subjects research, and thus, do not require IRB review or approval.
- The annual burden estimate has been revised downward by 933 hours from 1,777 hours in 2018 to 844 hours in 2021. We estimated interviewing 10 workers per restaurant in the last cycle; we have revised this down to five workers per restaurant.

There is no cost to the respondents other than their time. The total annual time burden requested is 844 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Retail managers	Manager Telephone Recruiting Script	889	1	3/60
	Manager Interview/Assessment	400	1	30/60
	Observation	400	1	30/60
Retail food workers	Worker Recruiting/Informed Consent Script	2,000	1	2/60
	Worker Interview/Assessment	2,000	1	10/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–17345 Filed 8–12–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–21–21HE; Docket No. CDC–2021–0081]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled One Health Case Investigation Form for Animals with SARS–CoV–2. This proposed information collection is designed to improve the scientific community's understanding of SARS–CoV–2 infections in animals.

DATES: CDC must receive written comments on or before October 12, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0081 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

One Health Case Investigation Form for Animals with SARS–CoV–2—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The proposed collection includes a standardized form that collects and compiles epidemiologic data on animals infected with SARS–CoV–2, including exposure history to people or other sources, clinical presentation, diagnostic testing data, and the risk the animal may pose of transmitting SARS–CoV–2 to human or animal hosts. The form is intended to guide state, tribal, local and territorial health officials conducting an epidemiological investigation when an animal with suspected or confirmed SARS–CoV–2 infection is identified. Data collected will focus primarily on animal subjects, and there is no Personal Identifiable Information (PII) requested on the form. Steps have been taken to minimize duplication of effort, including consultation with state, tribal, local, territorial, and federal partners (including USDA and FDA), and international agencies.

The epidemiological information on animals infected with SARS–CoV–2 that is collected will be used to refine guidance and recommendations, identify high-risk exposures and transmission events, and advance surveillance directives for future emerging infectious diseases. CDC requests approval for an estimated 1,000

annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State officials (state and local public health veterinarians and state animal health officials).	One Health Investigation Form-Animal Cases of SARS–CoV–2.	50	20	1	1,000

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–17352 Filed 8–12–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–21–0572]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Health Message Testing System (HMTS) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on May 26, 2021 to obtain comments from the public and affected agencies. CDC received one non-substantive comment. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Health Message Testing System (HMTS) (OMB Control No. 0920–0572, Exp. 8/31/2021)—Extension—Office of the Associate Director for Communication (OADC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Before CDC disseminates a health message to the public, the message always undergoes scientific review. However, even though the message is based on sound scientific content, there is no guarantee that the public will understand a health message or that the message will move people to take recommended action. Communication theorists and researchers agree that for health messages to be as clear and influential as possible, target audience members or representatives must be involved in developing the messages and provisional versions of the messages must be tested with members of the target audience.

Increasingly, there are circumstances when CDC must move swiftly to protect life, prevent disease, or calm public anxiety. Health message testing is even more important in these instances, because of the critical nature of the information need. In the interest of timely health message dissemination, many programs forgo the important step of testing messages on dimensions such as clarity, salience, appeal, and persuasiveness (*i.e.,* the ability to influence behavioral intention). Skipping this step avoids the delay involved in the standard OMB review process, but at a high potential cost. Untested messages can waste communication resources and opportunities because the messages can be perceived as unclear or irrelevant. Untested messages can also have unintended consequences, such as jeopardizing the credibility of Federal health officials.

The Health Message Testing System (HMTS), a Generic information collection, enables programs across CDC to collect the information they require in a timely manner to:

- Ensure quality and prevent waste in the dissemination of health information by CDC to the public,
- Refine message concepts and to test draft materials for clarity, salience, appeal, and persuasiveness to target audiences,
- Guide the action of health communication officials who are responding to health emergencies, Congressionally-mandated campaigns with short timeframes, media-generated public concern, time-limited communication opportunities, trends, and the need to refresh materials or dissemination strategies in an ongoing campaign,

Each testing instrument will be based on specific health issues or topics. Although it is not possible to develop one instrument for use in all instances, the same kinds of questions are asked in

most message testing. This package includes generic questions and formats that can be used to develop health message testing data collection instruments. These include a list of screening questions, comprised of demographic and introductory questions, along with other questions that can be used to create a mix of relevant questions for each proposed message testing data collection method. Programs may request to use additional questions if needed.

Message testing questions will focus on issues such as comprehension, impressions, personal relevance, content and wording, efficacy of response, channels, and spokesperson/sponsor. Such information will enable message developers to enhance the effectiveness of messages for intended audiences.

Data collection methods proposed for HMTS include intercept interviews, telephone interviews, focus groups, online surveys, and cognitive interviews. In almost all instances, data will be collected by outside organizations under contract with CDC.

For many years CDC programs have used HMTS to test and refine message concepts and test draft materials for clarity, salience, appeal, and persuasiveness to target audiences. Having this generic clearance available has enabled them to test their information and get critical health information from the public quickly. Over the last three years, more than 32 messages have been tested using this clearance. Examples include:

CDC Older Adult Injury Prevention Creative Campaign—Survey. This health communication campaign aimed to support and expand upon CDC's older adult injury prevention efforts and to raise awareness among older adults and their caregivers about preventable injuries that disproportionately impact them, steps to reduce their risk of injuries, and increase education about risk factors. Information collected can assist in the most effective use of CDC communication resources and opportunities by assessing clarity, appeal, persuasiveness and effectiveness of campaign material and advertisements (*i.e.,* poster or video advertisement).

The Division of Tuberculosis Elimination (DTBE) obtained OMB approval through HMTS for Health Communications Testing for Latent Tuberculosis Infections (LTBI) Campaign for CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. This collection was used to inform NCHHSTP/DTBE's future public service campaign efforts targeted to consumers at high-risk for LTBI, and the providers who serve them. This information collection activity is essential because it will provide CDC with effective messages for communicating about this disease and infection to motivate at-risk consumers to get preventive screening and, if infected, treatment, and to motivate healthcare providers to encourage testing and early detection.

The Division of Diabetes Translation obtained OMB approval through HMTS for Message Testing for Diabetes Self-Management Education and Support (DSMES) Marketing Support: Card Sort Activity. Findings from this message testing effort were used by the Centers for Disease Control and Prevention's (CDC) Division of Diabetes Translation (DDT) to inform how best to communicate with key audiences about DSMES services. Specifically, information about which attributes of DSMES services are most important to each audience will be identified and will serve as the basis for messages developed to promote DSMES services. This work will help increase the likelihood that messages will resonate and be understood as intended.

Over 27,696 respondents were queried and over 6,100 burden hours used during this time period. Because the availability of this ICR has been so critical to programs in disseminating their materials and information to the public in a timely manner, OADC is requesting a three-year extension of this information collection. Based on anticipated use, CDC requests approval for an estimated 2,470 annual burden hours (7,410 over the course of the three-year approval). There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public Health Professionals, Health Care Providers, State and Local Public Health Officials, Emergency Responders, General Public.	Moderator's Guides, Eligibility Screeners, Interview Guides, Opinion Surveys, Consent Forms.	18,525	1	8/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–17350 Filed 8–12–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–21–0222]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled The Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on May 26, 2021 to obtain comments from the public and affected agencies. CDC received no comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

The Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB Control No. 0920–0222, Exp. 08/31/2021)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall undertake and support (by grant or contract) research, demonstrations, and evaluations respecting new or improved methods for obtaining current data to support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

The Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) is the focal point within NCHS for questionnaire and survey development, pre-testing, and evaluation activities for CDC surveys such as: The National Survey of Family Growth (NSFG), the Research and Development Survey (RANDS) (including RANDS COVID), and other federally sponsored surveys.

The CCQDER and other NCHS programs conduct cognitive interviews, focus groups, in-depth or ethnographic interviews, usability tests, field tests/pilot interviews, and experimental research in laboratory and field settings, both for applied questionnaire development and evaluation, as well as more basic research on measurement errors and survey response.

Various techniques to evaluate interviewer-administered, self-administered, telephone, Computer-Assisted Personal Interviewing (CAPI), Computer Assisted Self-Interviewing (CASI), Audio Computer-Assisted Self-Interviewing (ACASI), and web-based questionnaires are used.

The most common questionnaire evaluation method is the cognitive interview. These evaluations are conducted by the CCQDER. The interview structure consists of respondents first answering a draft survey question and then providing textual information to reveal the processes involved in answering the test question. Specifically, cognitive interview respondents are asked to describe how and why they answered the question as they did. Through the interviewing process, various types of question-response problems that would not normally be identified in a traditional survey interview, such as interpretive errors and recall accuracy, are uncovered. By conducting a comparative analysis of cognitive interviews, it is also possible to determine whether particular interpretive patterns occur within particular sub-groups of the population. Interviews are generally conducted in small rounds totaling 40–100 interviews; ideally, the questionnaire is re-worked between rounds, and revisions are tested iteratively until interviews yield relatively few new insights.

Cognitive interviewing is inexpensive and provides useful data on questionnaire performance while minimizing respondent burden. Cognitive interviewing offers a detailed depiction of meanings and processes used by respondents to answer questions, a process that ultimately produces the survey data. As such, the method offers an insight that can transform understanding of question validity and response error. Documented findings from these studies represent tangible evidence of how the question performs. Such documentation also serves CDC data users, allowing them to be critical users in their approach and application of the data.

In addition to cognitive interviewing, a number of other qualitative and quantitative methods are used to investigate and research measurement errors and the survey response process. These methods include conducting focus groups, usability tests, in-depth or ethnographic interviews, and the administration and analysis of questions in both representative and non-representative field tests. Focus groups are conducted by the CCQDER. Focus groups are group interviews whose primary purpose is to elicit the basic sociocultural understandings and terminology that form the basis of questionnaire design. Each group typically consists of one moderator and 4–10 participants, depending on the research question. In-depth or ethnographic interviews are one-on-one interviews designed to elicit the understandings or terminology that are necessary for question design, as well as to gather detailed information that can contribute to the analysis of both qualitative and quantitative data. Usability tests are typically one-on-one interviews that are used to determine how a given survey or information collection tool functions in the field, and how the mode and layout of the instrument itself may contribute to survey response error and the survey response process.

In addition to these qualitative methods, NCHS also uses various tools to obtain quantitative data, which can be analyzed alone or analyzed alongside qualitative data to give a much fuller accounting of the survey response process. For instance, phone, internet, mail, and in-person follow-up interviews of previous NCHS survey respondents may be used to test the validity of survey questions and questionnaires and to obtain more detailed information that cannot be gathered on the original survey. Additionally, field or pilot tests may be conducted on both representative and non-representative samples, including those obtained from commercial survey and web panel vendors. Beyond looking at traditional measures of survey errors (such as item missing rates, non-response, and don't know rates), these pilot tests can be used to run

experimental designs in order to capture how different questions function in a field setting. Similar methodology has been adopted by other federal agencies, as well as by academic and commercial survey organizations.

In 2021–2024, NCHS/CCQDER staff plan to continue research on methods evaluation and general questionnaire design research. We envision that over the next three years, NCHS/CCQDER will work collaboratively with survey researchers from universities and other Federal agencies to define and examine several research areas, including, but not limited to: (1) Differences between face-to-face, telephone, and virtual/video over internet cognitive interviewing, (2) effectiveness of different approaches to cognitive interviewing, such as concurrent and retrospective probing, (3) reactions of both survey respondents and survey interviewers to the use of Computer-Assisted Personal Interviewing (CAPI), Audio Computer-Assisted Self-Interview (ACASI), video over internet/virtual, (4) social, cultural and linguistic factors in the question response process, and (5) recruitment and respondent participation at varying levels of incentive in an effort to establish empirical evidence regarding remuneration and coercion. Procedures for each of these studies will be similar to those applied in the usual testing of survey questions. For example, questionnaires that are of current interest (such as RANDS and NIOSH) may be evaluated using several of the techniques described above. In addition, different versions of a survey question will be developed, and the variants then administered to separate groups of respondents in order to study the cognitive processes that account for the differences in responses obtained across different versions.

These studies will be conducted either by CCQDER staff, DHHS staff, or NCHS contractors who are trained in cognitive interviewing techniques. The results of these studies will be applied to our specific questionnaire development activities in order to improve the methods that we use to conduct questionnaire testing, and to guide questionnaire design in general.

OMB approval is requested for three years. Participation is voluntary. We are requesting 9,455 annualized hours, totaling 28,365 over three years. This is an increase of 1,672 hours per year or 5,016 hours over three years. The requested increases are due to an anticipated increase in the number and size of projects being undertaken.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals or households	Eligibility Screeners	4,400	1	5/60
Individuals or households	Developmental Questionnaires	8,750	1	55/60
Individuals or households	Respondent Data Collection Sheet	8,750	1	5/60
Individuals or households	Focus Group Documents	225	1	90/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–17349 Filed 8–12–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–1880 and CMS–1856]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 13, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Request for Certification as Supplier of Portable X-Ray Services under the Medicare/Medicaid Program; *Use:* CMS–1880 is initially completed by suppliers of portable X-ray services, expressing an interest in and requesting participation in the Medicare program. The CMS–1880 form initiates the process of obtaining a decision as to whether the conditions of coverage are met by the portable X-ray supplier seeking Medicare participation. It also promotes data reduction or introduction to, and retrieval from, the Certification and Survey Provider Enhanced Reporting (CASPER) by the CMS Regional Offices (ROs). The CMS–1880 form is also completed by current Medicare participating portable x-ray supplier during each recertification survey. *Form Numbers:* CMS–1880 (OMB control number: 0938–0027); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 104; *Total Annual Responses:* 104; *Total Annual Hours:* 26. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Certification in the Medicare/Medicaid Program for Provides of Outpatient Physical Therapy and/or Speech-Language Pathology; *Use:* The form is used as an application to be completed by providers of outpatient physical therapy and/or speech-language pathology services requesting participation in the Medicare and Medicaid programs. This form initiates the process of obtaining a decision as to whether the conditions of participation are met as a provider of outpatient physical therapy and/or speech-language pathology services. The form is used by the State Agencies (SAs) to enter the new prospective provider into the national surveyor database. The form is also used for recertification of the provider. Surveyors are no longer required to use form CMS–1856. Surveyors are now able to access survey resources electronically from the national surveyor database, as a result, the need for surveyors to carry printed copies of the survey information data is no longer efficient. *Form Number:* CMS–1856 (OMB control number: 0938–0065); *Frequency:* Annually, occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 195; *Total Annual Responses:* 195; *Total Annual Hours:* 49. (For policy questions regarding this collection contact Caecilia Blondiaux at 410–786–2190.)

Dated: August 10, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–17374 Filed 8–12–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1245]

Drug Products Approved in Abbreviated New Drug Applications Before the Enactment of the Hatch-Waxman Amendments; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a public docket to solicit comments on several issues related to FDA's post-approval regulation of certain drug products approved in abbreviated applications before the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish the current abbreviated new drug application (ANDA) process. Because these pre-Hatch-Waxman abbreviated new drug applications (referred to in this notice as ''PANDAs'') were submitted and approved under the provisions of the FD&C Act that apply to 505(b) new drug applications, they can serve as a reference listed drug (RLD) for ANDAs and can also be a listed drug relied on by 505(b)(2) applications. PANDAs have historically been overseen by FDA's Office of Generic Drugs, and FDA is aware that there may be some confusion about the applicability of certain statutory and regulatory provisions to PANDAs. FDA is seeking input from holders of PANDAs and other interested persons regarding whether there are regulatory or policy rationales for treating PANDAs differently from other 505(b) applications in certain respects.

DATES: Submit either electronic or written comments by December 13, 2021.

ADDRESSES: FDA is establishing a docket for public comments on this document. The docket number is FDA–2020–N–1245. The docket will close on December 13, 2021. Submit either electronic or written comments by that date. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 13, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 13, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1245 for ''Drug Products Approved in Abbreviated New Drug Applications Before the Enactment of the Hatch-Waxman Amendments; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Melissa Mannion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Room 1611, Silver Spring, MD 20993, 301–796–2747, *Melissa.Mannion@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Abbreviated New Drug Applications Before the Hatch-Waxman Amendments

After the enactment of the FD&C Act (Pub. L. 75–717) in 1938, new drug products were required to be approved on the basis of safety before they could be marketed. Between 1938 and 1962, if a drug product obtained approval, FDA considered drug products that were identical, related, or similar to the approved product to be covered by that approval; such identical, related, or similar products were marketed without independent approval. An identical, related, or similar drug includes another brand, potency, dosage form, salt, or ester of the same drug moiety related in chemical structure or known pharmacological properties (see 21 CFR 310.6(b)(1)). In 1962, the Kefauver-Harris Drug Amendments (Pub. L. 87–781) amended the FD&C Act to require that new drug products also be shown to be effective in order to obtain approval of a new drug application (NDA). After the enactment of the Kefauver-Harris Drug Amendments, FDA initiated the Drug Efficacy Study Implementation (DESI) to evaluate the effectiveness of drug products that had been approved between 1938 and 1962 solely on the basis of safety. DESI also covered the identical, related, or similar products that had entered the market without approval. If drug products were determined to be effective for one or more indications,[1] manufacturers that were already marketing under an NDA were required to submit a supplement to update the application and revise the product labeling as necessary. Manufacturers of drug products that were identical, related, or similar were required to submit applications for their drug products.

FDA introduced the concept of an ''abbreviated new drug application'' in 1968[2] as a vehicle for approval of certain drugs affected by the DESI review, and in 1970, FDA published a final rule establishing a regulatory pathway for submission of abbreviated applications for these drugs (see 35 FR 6574 (April 24, 1970); see also 34 FR 2673 (February 27, 1969)). This abbreviated approval mechanism was created to offer manufacturers of certain drugs a streamlined and more administratively efficient path to seek FDA approval as part of the DESI review (47 FR 46622 at 46631 to 46632 (October 19, 1982)).

When a drug product subject to the DESI review was determined to be effective for one or more indications, FDA would issue a **Federal Register** notice (DESI notice) for that drug product describing the DESI review findings and stating whether abbreviated new drug applications that met specified criteria could be submitted to FDA (see generally 35 FR 11273 (July 14, 1970); 35 FR 6574) for products that had not been marketed under an NDA. Such a finding allowed manufacturers to submit an abbreviated new drug application (*i.e.,* a PANDA) in lieu of an NDA.

For approval of PANDAs, FDA relied on the evidence of effectiveness that had been provided, reviewed, and accepted during the DESI process. FDA evaluated the safety of these drug products on the basis of information included in NDAs submitted prior to 1962, as well as the subsequent marketing experience with the drugs (see 54 FR 28872 at 28873 (July 10, 1989)). PANDAs were submitted under section 505(b) of the FD&C Act and approved under section 505(c) of the FD&C Act.[3]

[1] If a drug product was found to be less than effective for one or more labeled indications in FDA's initial DESI review, the Agency provided an opportunity to submit additional data and eventually an opportunity for a hearing on those indications found to be less than effective. FDA considered the basis of any hearing request and either granted or denied the hearing request and published its final determination in the **Federal Register**. If FDA's final determination classified a drug product as effective for an indication, those marketing that drug product and drugs identical, related or similar to it were required to obtain approved applications for continued marketing for that indication. If FDA's final determination classified the drug product as lacking substantial evidence of effectiveness for an indication, the product and those identical, related or similar to it could no longer be legally marketed for that indication.

[2] See the Washington briefing on FDA's drug efficacy review, FDA Papers, at pp. 10–12 (March 1968) and Address of Commissioner James L. Goddard, M.D., at the Alpha Omega Alpha Lecture at Yale New Haven Medical Center on New Drug Research and Development (April 17, 1968).

[3] The content of section 505(b) of the FD&C Act regarding the required contents of an application remained largely unchanged following the enactment of the Hatch-Waxman Amendments, except for changes related to new patent submission requirements and, for applications submitted

Because the history of FDA review of applications for antibiotic drug products is more complex and historically many were subject to section 507 of the FD&C Act (21 U.S.C. 357 (1994 ed.); repealed upon the enactment of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115)), the scope of this notice is limited to drug products approved in PANDAs under section 505 of the FD&C Act prior to the Hatch-Waxman Amendments; this notice does not cover applications for antibiotic drug products that were originally submitted under section 507 of the FD&C Act.[4]

Because PANDAs could be for products that were ''similar or related'' to, and not just ''duplicates'' [5] of, drug products approved in NDAs before October 10, 1962, and listed in DESI notices (pre-1962 NDA drug products), FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (Orange Book) lists both unique products approved in PANDAs (*i.e.,* no NDA was ever approved for the identical drug product), and products approved in PANDAs that may be duplicates of pre-1962 NDA drug products. In the Orange Book, a product approved in a PANDA typically is identified as an ''ANDA.'' (The application type for a product is identified in the Orange Book by either an ''*N*'' (for an NDA) or an ''*A*'' (for an ANDA) before the application number.)

Although the regulations establishing the pathway for PANDAs were similar in some respects to the ANDA pathway created by the Hatch-Waxman Amendments and described in section 505(j) of the FD&C Act, the requirements under the old regulatory pathway (which evolved over the decade-plus in which it was operational before the Hatch-Waxman Amendments) also differed in many respects from current ANDA requirements. For example, although the conditions of use and labeling for PANDA products had to be in accord with the relevant DESI notice (which frequently covered a class of drugs that included multiple products and multiple active ingredients) (see, *e.g.,* 36 FR 11227 (June 10, 1971); 35 FR 18215 (November 28, 1970); and 35 FR 12356 (August 1, 1970)), PANDA products were not required to have the same labeling as a particular pre-1962 NDA drug product listed in the DESI notice. In addition, although PANDAs were required to include adequate data to assure biological availability of the drug if the relevant DESI notice for that drug specified that such data should be submitted for the formulation intended for marketing, PANDAs generally did not have to include data to demonstrate bioequivalence to a particular pre-1962 NDA drug product (see, *e.g.,* 21 CFR 130.4(f)(3) (1971 ed.) and 21 CFR 314.2(f)(3) (1984 ed.)). In addition, drug products with a different formulation, active ingredient, route of administration, dosage form, or strength than the pre-1962 NDA drug products listed in the DESI notice could be submitted in PANDAs. Prior to the Hatch-Waxman Amendments, there were also no requirements related to patent listing or patent certification or exclusivity for PANDAs or other applications approved under section 505(c) of the FD&C Act.

B. Hatch-Waxman Amendments

In 1984, the Hatch-Waxman Amendments added section 505(b)(2) and section 505(j) to the FD&C Act. These sections provide an abbreviated approval pathway for submission of two types of applications: Section 505(b)(2) new drug applications (505(b)(2) applications) and section 505(j) abbreviated new drug applications (for purposes of this notice, referred to hereinafter as ''505(j) ANDAs''). A 505(b)(2) application is an NDA submitted under section 505(b)(1) and approved under section 505(c) of the FD&C Act that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (*e.g.,* the Agency's finding of safety and/or effectiveness for a listed drug). A 505(j) ANDA is an application that requests FDA approval to market a duplicate of a listed drug.[6] Regulations implementing the Hatch-Waxman Amendments define a *listed drug* as a new drug product that has been approved under section 505(c) of the FD&C Act for safety and effectiveness or under section 505(j) of the FD&C Act, which has not been withdrawn or suspended under section 505(e)(1) through (5) or section 505(j)(6) of the FD&C Act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's identification in the current edition of FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (the list) as an approved drug. A drug product is deemed to be a listed drug on the date of approval for the NDA or ANDA for that drug product. (See § 314.3(b) (21 CFR 314.3(b)), as amended at 81 FR 69580 at 69638 (October 6, 2016); see also section 505(j)(2)(A), (j)(7) of the FD&C Act).

FDA regulations require an applicant to refer in its 505(j) ANDA to the specific listed drug on which the applicant relies in seeking approval of the 505(j) ANDA (§ 314.94(a)(3) (21 CFR 314.94(a)(3)); see also section 505(j)(2) of the FD&C Act). The listed drug that a generic applicant seeks to duplicate is commonly referred to as the *reference listed drug* (RLD) (see definition in § 314.3(b)). A 505(j) ANDA applicant must show, among other things, that the proposed generic drug is bioequivalent to the RLD, and that it has the same active ingredient(s), conditions of use, route of administration, dosage form, strength, and (with limited exceptions) labeling as the RLD (section 505(j)(2)(A), (j)(2)(C), and (j)(4) of the FD&C Act; see also § 314.94(a)). We note that certain differences between an RLD and a proposed generic drug product may be permitted in an ANDA if these differences are the subject of an approved suitability petition (see section 505(j)(2)(C) of the FD&C Act and 21 CFR 314.93). An applicant may submit a suitability petition to FDA requesting permission to submit an ANDA for a generic drug product that differs from an RLD in its route of administration, dosage form, or strength or that has one different active ingredient in a fixed-combination drug product (ibid.).

Because a 505(j) ANDA applicant is relying on FDA's finding that the RLD

pursuant to section 505(b)(2) of the FD&C Act, patent certification requirements.

[4] Prior to the enactment of the Food and Drug Administration Modernization Act of 1997, applications for antibiotic drugs were generally approved for safety and effectiveness under section 507 of the FD&C Act rather than under section 505 of the FD&C Act. For purposes of section 507, the term ''*antibiotic drug*'' was defined as any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance). See 21 U.S.C. 357 (1964 ed.; 1994 ed.). Although there was a mechanism for approving abbreviated applications for antibiotics under section 507 that pre-dated the Hatch-Waxman Amendments, in this notice the term *PANDAs* refers only to those applications submitted under section 505(b) of the FD&C Act, and not to applications for antibiotic drug products submitted under section 507 of the FD&C Act. FDA intends to address these antibiotic products separately.

[5] In the context of PANDAs, the term '*duplicate*' applied to a drug product that was the same as an already approved drug product in dosage form, route of administration, kind and amount of active ingredient, indication(s), and any other conditions of use. See 54 FR 28872 at 28872 (July 10, 1989).

[6] In the context of the Hatch-Waxman Amendments, the term *duplicate* generally refers to a ''drug product that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use as a listed drug . . .'' 54 FR 28872 at 28877.

is safe and effective, FDA's general practice is to designate as RLDs drug products that have been approved under section 505(c) for safety and effectiveness. Similarly, FDA regulations require a 505(b)(2) applicant to identify in its application each listed drug for which FDA has made a finding of safety and effectiveness on which the applicant relies in seeking approval of its proposed drug product (21 CFR 314.54(a)(1)(iii)).

Listed drugs appear in the Orange Book, and beginning in 1992, the Orange Book also began identifying which listed drugs were designated as RLDs to aid 505(j) ANDA applicants. The listed drugs that were designated as RLDs were labeled with a ''+'' sign in the paper version of the Orange Book, and with the word ''Yes'' in the column titled RLD in the electronic version of the Orange Book. Before 2017, the ''+'' sign and the word ''Yes'' in the column labeled RLD were used to denote at times an RLD and at other times a reference standard, which is the drug product selected by FDA that an applicant seeking approval of a 505(j) ANDA must use in conducting an in vivo bioequivalence study required for approval of the ANDA (§ 314.3(b)).

The reference standard selected by FDA is ordinarily the RLD. However, at times the reference standard is a drug product other than the RLD. For example, if the NDA RLD is no longer marketed, FDA generally will select as the reference standard a previously approved 505(j) ANDA that refers to that RLD. Where the RLD was no longer marketed and FDA selected a new reference standard, FDA's practice prior to 2017 was to identify the reference standard with the ''+'' sign in the paper version of the Orange Book and ''Yes'' in the RLD column of the electronic version of the Orange Book; FDA also would move the previously identified RLD to the discontinued section of the Orange Book without a ''+'' sign in the paper version or RLD designation in the electronic version of the Orange Book.

Because the ''+'' sign or RLD designation in some cases identified drug products that were RLDs as well as reference standards, and in other cases identified reference standards that were not also the RLD, there may have been some confusion among 505(j) ANDA applicants about which product to cite as the RLD when the reference standard and RLD were not the same drug product. Inconsistent use of terminology, as well as certain long-standing FDA practices, may have added to this confusion.

C. FDA's Current Identification of RLDs and Reference Standards in the Orange Book

In 2017, FDA began to separately identify in the Orange Book which listed drugs, including some in the ''Discontinued Drug Product List'' (discontinued section), are designated as RLDs, and which listed drugs in the Active Section (*i.e.,* in the sections entitled ''Prescription Drug Product List'' and ''Over-the-Counter Drug Product List'') are selected as reference standards. In the electronic version of the Orange Book, there is one column that identifies RLDs and a separate column that identifies reference standards. In the printed version of the Orange Book, the RLDs and reference standards are identified by distinct symbols.

These changes to the Orange Book were intended to provide clarity to 505(j) ANDA applicants as to which listed drugs are the RLDs (versus the reference standards) for a drug product. For some drug products, however, these changes revealed that no product is identified as being approved under an NDA (in either the active or discontinued sections of the Orange Book) that could serve as an RLD for a 505(j) ANDA. The lack of an RLD is confusing because the Orange Book reflects that there are approved ANDAs for the drug product, including ANDAs identified as reference standards. One reason for this lack of an RLD is that some of the products listed in the Orange Book and identified as being approved in an ''ANDA'' are actually drugs that were approved for safety and effectiveness under section 505(c) of the FD&C Act in PANDAs that appeared to have been identified as RLDs before the 2017 update to the Orange Book. As noted previously, products approved in PANDAs could be unique products that differed from products approved under pre-1962 NDAs in various ways, including in their active ingredient, route of administration, dosage form, or strength. In addition, even when certain listed drugs approved in a PANDA appear to be pharmaceutical equivalents (as defined in § 314.3(b)) of products approved under an NDA, these products can differ from the products approved under the NDA in other respects, including in the approved conditions of use reflected in the labeling or in their formulation, and may not have been determined to be bioequivalent to the products approved under an NDA. Further, even if the drug product approved in a PANDA was a duplicate of a drug product that was at one time also approved and marketed under an NDA, if the product approved under the NDA was no longer marketed when the Orange Book was first published in October 1980, it was not listed in the Orange Book.

D. Designation of Additional Drugs as RLDs

In light of the changes to the Orange Book in 2017, FDA examined the types of products for which there were no RLDs designated and determined that many were approved in PANDAs. After consideration of the history of PANDAs, FDA determined that it was appropriate and consistent with FDA's general practice regarding the designation of RLDs to designate PANDA products as RLDs because these products were approved for safety and effectiveness under section 505(c) of the FD&C Act. In addition, as noted in section I.C, many of these products appeared to have been identified as RLDs before the 2017 update to the Orange Book. Designation of the PANDA products as RLDs provides clarity both to prospective 505(j) ANDA applicants seeking to make generic versions of these products, and to applicants of 505(b)(2) applications that there is a finding of safety and effectiveness for these products that may be relied upon for approval. In addition, it is aligned with FDA's efforts to help advance competition and increase patient access to more affordable medicines.

FDA has begun adding RLD designations for PANDAs to the Orange Book and will continue making these designations as expeditiously as resources permit. If a prospective 505(j) ANDA applicant is seeking to duplicate a product approved in a PANDA that has not yet been designated as an RLD by FDA, the prospective applicant may submit controlled correspondence to FDA identifying the drug it intends to duplicate and asking FDA to designate that drug as an RLD (see FDA's guidance for industry, ''Controlled Correspondence Related to Generic Drug Development,'' announced in 85 FR 81928 (December 17, 2020)).[7]

To aid stakeholders in identifying PANDAs, FDA has posted a list of the products currently included in the Orange Book and identified as an ''ANDA'' in the Orange Book that were approved in a PANDA for safety and effectiveness under section 505(c) prior to the enactment of the Hatch-Waxman Amendments. This list includes only PANDAs described in this notice, *i.e.,*

[7] For the most recent version of a guidance, check the FDA guidance web page at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

those abbreviated applications submitted under section 505(b) of the FD&C Act and does not include applications for antibiotic drug products approved under section 507 of the FD&C Act before the enactment of the Food and Drug Administration Modernization Act of 1997 (FDAMA). This list is available under ''Additional Resources'' on FDA's ''Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)'' web page (available at *https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book*). In addition, the Orange Book provides information about the approval date of listed drugs,[8] allowing interested persons to refer to this information to determine which products identified as being approved in an ANDA in the Orange Book were approved before the enactment of the Hatch-Waxman Amendments.[9]

II. Additional Issues for Consideration and Request for Comments

The Agency is seeking input from holders of PANDAs and other interested stakeholders on several issues related to FDA's post-approval regulation of drug products approved in PANDAs. As explained in section I of this notice, PANDAs were submitted under section 505(b) and approved under section 505(c) of the FD&C Act, which are the same provisions under which NDAs are submitted and approved. However, PANDA products have historically been overseen by FDA's Office of Generic Drugs and are included in the definition of *abbreviated new drug application* for user fee purposes under the Generic Drug User Fee Amendments (GDUFA),[10] which specify that this term includes an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984 (see 21 U.S.C. 379j–41). PANDAs are not included in the FD&C Act statutory definition of the term *abbreviated drug application,* which is limited to applications submitted under section 505(j) of the FD&C Act (see 21 U.S.C. 321(aa)).

FDA recognizes that PANDAs may have been treated similarly to 505(j) ANDAs in some respects over the decades after the enactment of the Hatch-Waxman Amendments, and that there may be confusion among holders of PANDAs about the applicability of certain statutory and regulatory provisions to their products and in particular, whether their products are subject to the requirements that apply to other 505(b) applications or to those that apply to 505(j) applications (to the extent there are differences between the two), including with respect to requirements regarding labeling updates, patent listing, eligibility for exclusivity, and certain drug safety-related requirements or procedures.

For example, with respect to labeling updates, FDA is aware that some PANDA holders have followed procedures applicable to 505(b) applications when proposing labeling updates for their products (*e.g.,* submitting labeling supplements and making labeling changes independent of the pre-1962 NDA product or products that were listed in the DESI notice). However, FDA is also aware that some PANDA holders have followed procedures applicable to 505(j) ANDA holders when proposing labeling updates for their products (*e.g.,* submitting labeling supplements to conform to labeling changes approved for a pre-1962 NDA product listed in a relevant DESI notice).

With respect to patent listing, to FDA's knowledge, PANDA holders have neither sought to list patent information in the Orange Book for their products after the enactment of the Hatch-Waxman Amendments, nor have they submitted patent listing information when submitting supplements to their approved applications during the years after the enactment of the Hatch-Waxman Amendments. Similarly, PANDA holders have generally not submitted supplements containing reports of new clinical investigations or sought exclusivity under provisions applicable to 505(b) applications (see, *e.g.,* section 505(c)(3)(E)(iv) and 505(j)(5)(F)(iv) of the FD&C Act) following enactment of the Hatch-Waxman Amendments.

FDA is also aware that there may be confusion among PANDA holders about the applicability of certain safety-related requirements to their applications. For example, section 505(o) of the FD&C Act, which relates to postmarket studies and clinical trials and labeling, and section 505–1 of the FD&C Act, which relates to risk evaluation and mitigation strategies, reflect some differences in the safety-related requirements or procedures that apply to 505(b) application holders versus 505(j) ANDA holders, and PANDA holders may consider the requirements that apply to 505(j) ANDA holders to also apply to their applications.

Although, as noted in section I of this notice, PANDAs are section 505(b) applications, FDA understands, as outlined above, that the holders of some PANDAs may have been following various requirements applicable to 505(j) ANDAs over the years after the enactment of the Hatch-Waxman Amendments, and that for them to instead follow requirements applicable to 505(b) applications could be a change in practice. FDA also understands that PANDAs are a unique category of 505(b) applications and that there could be valid reasons to treat PANDAs differently from other 505(b) applications in certain circumstances, to the extent permitted by the applicable statutory provisions.

FDA is seeking input from PANDA holders and other interested stakeholders on whether there are regulatory or policy reasons for treating PANDAs differently from other 505(b) applications, consistent with the statutory requirements for applications submitted under section 505(b) and approved under section 505(c) of the FD&C Act. To facilitate this input, FDA has developed the following list of questions. These questions are not meant to be exhaustive, and FDA is also

[8] For products approved prior to January 1, 1982, the electronic version of the Orange Book indicates the product was ''Approved Prior to Jan. 1, 1982'' under Product Details in the Approval Date field, and the printed version of the Orange Book has a blank Approval Date field. For products approved on or after January 1, 1982, the electronic and printed versions of the Orange Book provide the specific date of approval in the Approval Date field.

[9] The Hatch-Waxman Amendments were signed into law on September 24, 1984. PANDAs that were submitted before September 24, 1984, were processed by FDA in accordance with the procedures that existed before the passage of the Hatch-Waxman Amendments. See November 16, 1984, letter to interested persons from Harry M. Meyer, Jr., M.D., Director, FDA's Center for Drugs and Biologics. The list of PANDAs posted on FDA's Orange Book web page (*https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book*) includes all the abbreviated applications approved on or before September 24, 1984. FDA is aware that certain applications submitted before this date but approved after this date and identified as ANDAs in the Orange Book were approved under section 505(c) of the FD&C Act; FDA will update this list as appropriate to include such applications. If a prospective 505(j) ANDA applicant is seeking to duplicate a product approved after September 24, 1984, and the applicant believes the application for the product was submitted before that date and approved under section 505(c) of the FD&C Act, the prospective applicant may submit controlled correspondence to FDA identifying the drug they intend to duplicate and asking FDA to designate that drug as an RLD. The controlled correspondence should include any information known to the prospective applicant that supports the belief that the identified drug was approved in a PANDA. When FDA receives such designation requests, it will evaluate whether the product was approved under section 505(c) of the FD&C Act in determining whether to grant the request.

[10] See Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) and Title III of the FDA Reauthorization Act of 2017 (Pub. L. 115–52).

interested in any other pertinent information stakeholders would like to share on this topic. In all cases, FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information.

Questions

1. Given the legal requirements in place for applications submitted under section 505(b) and approved under section 505(c) of the FD&C Act, are there regulatory or policy rationales for treating PANDAs differently from other 505(b) applications in certain respects, in particular with respect to the following:

1.1. Labeling requirements, including requirements related to updating product labeling to reflect certain types of newly acquired safety-related information by submitting a ''changes being effected'' (CBE–0) supplement to FDA?

1.2. Patent listing requirements?

1.3. Eligibility for exclusivity?

1.4. Certain safety-related requirements, such as the postmarket studies and clinical trials or safety-labeling change requirements in section 505(o) of the FD&C Act or the risk evaluation and mitigation strategies requirements in section 505–1 of the FD&C Act?

In responding to the questions above, please provide a specific rationale for treating these applications differently.

2. To the extent that PANDA holders are expected to make changes to their current practices, what factors should FDA consider in determining a reasonable amount of time for PANDA holders to make such changes to their practices?

3. Are there additional steps FDA should take to highlight for PANDA holders that their ''abbreviated new drug application'' is a PANDA, *i.e.,* that it is a 505(b) application?

4. Are there additional steps FDA should take beyond posting the list on the Orange Book website to aid other interested persons in identifying PANDAs?

5. Are modifications needed to the list of PANDAs posted on the Orange Book website for accuracy? For example, are some PANDAs missing from the list?

6. Are there other issues FDA should consider in assessing the regulatory framework for PANDAs under the FD&C Act? Please provide specific examples and explain FDA's authority to address these issues.

Dated: August 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–17378 Filed 8–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: September 9, 2021.

Open: 10:00 a.m. to 2:30 p.m.

Agenda: Report of the Director, NICDR and concept clearances.

Place: National Institutes of Health, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Closed: 2:45 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892, 301–594–4805, *adombroski@nidcr.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nidcr.nih.gov/about,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: August 9, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–17302 Filed 8–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: September 14–15, 2021.

Open: September 14, 2021, 12:00 p.m. to 4:30 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion of NIMH program.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Closed: September 15, 2021, 11:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Tracy Lynn Waldeck, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, Neuroscience Center, 6001 Executive Boulevard, Room 4133, Rockville, MD 20892, (301) 480–6833, *waldeckt@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 9, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–17323 Filed 8–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Integrative Neuroscience Initiative on Alcoholism (INIA) Consortia (RFA AA 21–011,012,013) Review Panel B.

Date: October 19, 2021.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2116, MSC 6902, Bethesda, MD 20817, (301) 443–0800, *bbuzas@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: August 9, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–17301 Filed 8–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Project: Minority AIDS Initiative-Management Reporting Tools (MAI–MRTs)—(OMB No. 0930–0357)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) is requesting from the Office of Management and Budget (OMB) approval for the revised Minority AIDS Initiative (MAI) monitoring tools, which includes both youth and adult questionnaires, as well as the quarterly progress report. This revision includes the inclusion of new cohorts, substantial revisions to the youth and adult questionnaires, updates to the data used to estimate response rates and expected numbers of participants by service duration (see Table 1 below).

The cohorts of grantees funded by the MAI and included in this clearance request are:

- Capacity Building Initiative 2017
- Capacity Building Initiative 2018
- Prevention Navigators 2017
- Prevention Navigators 2019
- Prevention Navigators 2020
- Prevention Navigators 2021

The target population for the grantees will be at-risk minority adolescents and young adults. All MAI grantees are expected to report their monitoring data using SAMHSA's Strategic Prevention Framework (SPF) and to target minority populations, as well as other high-risk groups residing in communities of color with high prevalence of Substance Abuse and HIV/AIDS. The primary objectives of the monitoring tools include:

- Assess the success of the MAI in reducing risk factors and increasing protective factors associated with the transmission of the Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and other sexually transmitted diseases (STD).
- Measure the effectiveness of evidence-based programs and infrastructure development activities such as: Outreach and training, mobilization of key stakeholders, substance abuse and HIV/AIDS counseling and education, testing, referrals to appropriate medical treatment and/or other intervention strategies (*i.e.,* cultural enrichment activities, educational and vocational resources, social marketing campaigns, and computer-based curricula).
- Investigate intervention types and features that yield the best outcomes for specific population groups.

- Assess the extent to which access to health care was enhanced for population groups and individuals vulnerable to behavioral health disparities residing in communities targeted by funded interventions.
- Assess the process of adopting and implementing the SPF with the target populations.
- Added questions to capture details on the intervention and the referrals to the record management section (completed by grantee staff).

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN

Type of respondent activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Quarterly Progress Report	197	4	732	4	2,928
Adult questionnaire	10,000	2	20,000	.20	4,000
Youth questionnaire	2,500	2	5,000	.20	1000
Total	12,697		25,732		7,928

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–A, Rockville, Maryland 20857, *OR* email a copy to *carlos.graham@samhsa.hhs.gov.* Written comments should be received by October 12, 2021.

Carlos Graham,

Clearance Officer.

[FR Doc. 2021–17290 Filed 8–12–21; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6278–N–01]

HUD Program Evaluation Policy—Policy Statement

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: This policy statement articulates the core principles and practices of the Department of Housing and Urban Development's evaluation and research activities. This policy reaffirms HUD's commitment to conducting rigorous, relevant evaluations and to using evidence from evaluations to inform policy and practice.

DATES: August 13, 2021.

FOR FURTHER INFORMATION CONTACT: For information about this notice, contact Todd M. Richardson, Evaluation Officer, Office of Policy Development and Research, U.S. Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410, telephone (202) 402–5922. The listed telephone number is not a toll-free number. Persons with hearing- or speech-impairments may access this number through TTY by calling Federal Relay Service at 1–800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Evaluation activity occurs in several offices at HUD, but the special mission of HUD's Office of Policy Development and Research (PD&R) is to inform HUD policy development and implementation to improve life in American communities through conducting, supporting, and sharing research, surveys, demonstrations, program evaluations, and best practices. Within HUD, PD&R is responsible for most, but not all, program evaluations. The office provides reliable and objective data and analysis to help inform policy decisions.

In July 2016, GAO issued a report entitled ''Department of Housing and Urban Development: Actions Needed to Incorporate Key Practices into Management Functions and Program Oversight,'' (GAO 16–497) in which GAO presented a broad assessment of HUD's management of its operations and programs.[1] In the report, GAO examined HUD efforts to: (1) Meet Federal requirements and implement key practices for management functions, including performance planning and reporting and human capital, financial, acquisition, and information technology (IT) management; and (2) oversee and evaluate programs.

PD&R is the primary office within HUD responsible for data analysis, research, program evaluations, and policy studies that inform the development and implementation of programs and policies across HUD offices. PD&R undertakes program evaluations, often by using a process that includes convening expert panels. However, GAO found that PD&R had neither developed agency-wide, written policies for its program evaluations, nor documented the criteria used to select the expert panels and review the quality of program evaluations.

On December 6, 2016 (81 FR 87949), HUD issued a policy statement in the **Federal Register**[2] responding to the GAO report by setting out the core principles and practices of PD&R's evaluation and research activities. This statement incorporated some language from a policy statement by the Office of Policy, Research, and Evaluation of the Administration for Children and Families of the U.S. Department of Health and Human Services.

On January 14, 2019, the Foundations for Evidence-Based Policymaking Act of 2018 (''Evidence Act''), Public Law 115–435, was enacted.[3] Section 101 of the Evidence Act created 5 U.S.C. 311–315 and mandated that the head of each agency appoint an Evaluation Officer, including at HUD. This officer must establish common standards for all HUD evaluations, whether performed by PD&R or another office. This issuance articulates department-wide evaluation standards and states other new principles based on PD&R's experience since the November 2016 publication.

II. HUD Program Evaluation Policy

Section 101 of the Evidence Act defines ''evaluation'' to mean ''an assessment using systematic data collection and analysis of one or more programs, policies, and organizations intended to assess their effectiveness and efficiency.''

HUD has identified the following core principles and practices as fundamental to ensuring high-quality and consistent evaluation results: Rigor, relevance, transparency, independence, ethics, and technical innovation. This policy applies to all HUD-sponsored

[1] See *http://www.gao.gov/assets/680/678551.pdf.*

[2] *https://www.federalregister.gov/d/2016-29215.*

[3] *https://www.congress.gov/115/plaws/publ435/PLAW-115publ435.pdf.* See also the website, at *https://www.congress.gov/bill/115th-congress/house-bill/4174,* on the bill, H.R. 4174 of the 115th Congress, that became the Act.

evaluations and regulatory impact analyses; they also apply to the selection of projects, contractors, and HUD staff that are involved in evaluations.

Rigor

HUD is committed to using the most rigorous methods that are appropriate to the evaluation questions and feasible within budget and other constraints. The need for rigor is not restricted to impact evaluations; rigor is also necessary in implementation or process evaluations, descriptive studies, outcome evaluations, and formative evaluations; in both qualitative and quantitative approaches. Rigor requires ensuring that inferences about cause and effect are well founded (internal validity); requires clarity about the populations, settings, or circumstances to which results can be generalized (external validity); requires that researchers seek to understand and correct for implicit bias in the formulation of research questions and methods; and requires the use of measures that accurately capture the intended information (measurement reliability and validity). Implicit biases are discriminatory biases that reflect unidentified traces of past experience, including implicit attitudes that affect feelings, thoughts or actions, and implicit stereotypes that affect how others are characterized. Survey instruments are pre-tested with members of the population to be studied to increase measurement validity. When statistically appropriate, and particularly if the number of hypotheses being tested is large, HUD will require the use of commonly accepted adjustments to classical statistical testing to reduce the probability that random outliers are presented as meaningful.

In assessing the effects of programs or services, HUD evaluations use methods that isolate to the greatest extent possible the impacts of the programs or services from other influences, such as trends over time, geographic variation, or pre-existing differences between participants and non-participants. Where feasible, research should employ a treatment group and a counterfactual. A treatment group is a population that has received an intervention. A counterfactual is a population that did not receive the intervention and can credibly represent what would have happened to the treatment group in the absence of the intervention according to the above standard for rigor. For such causal questions, experimental approaches are preferred. When experimental approaches are not feasible, HUD uses the most rigorous approach that is feasible.

In both quantitative and qualitative research, rigor means having clear research questions and an explicit analytic framework; justification for case selection and sampling methods in relation to research goals; and transparent, verifiable methods of systematic data collection and analysis, auditable records, and attention to possible alternative interpretations during analysis and writing.

HUD ensures that contractors and grantees conducting evaluations have appropriate expertise through emphasizing the requirement for rigor in requests for proposals and funding opportunity announcements, noting that applicants' capacity for rigor will be evaluated in the selection process. In addition, HUD will judge research teams with equal capacity for rigor to be more qualified if the team includes researchers demographically similar to or knowledgeable about the perspectives and lived experiences of the populations studied.

HUD employs a strategic human capital development plan to hire, train, and retain a workforce that ensures staff have the tools and resources to accomplish the mission.

Relevance

The HUD evaluation agenda reflects the legislative requirements and policy issues related to HUD's mission. HUD solicits input from stakeholders, both internal and external, including stakeholders with lived experience, such as program participants, and grantees, on the selection of programs to be evaluated, initiatives, demonstrations, and research questions. For new initiatives and demonstrations in particular, evaluations will be more feasible and useful when planned in advance, in concert with the development of the initiative or demonstration, rather than as an afterthought. HUD strives to understand the relevance of its completed research through concerted stakeholder engagement, including with people and grantees affected by HUD programs, to continuously improve its research agenda.

Expert panels include research and other subject matter experts and are diverse in ways tailored to the study, including racial and ethnic diversity and representatives of the studied populations.

HUD strives to design program evaluations and other analyses to better understand structural racism and to reveal unequal benefits and harms across social groups as relevant, with special attention to race, national origin, color, familial status, religion, disability, age, and sex (including gender identity and sexual orientation).

To support this goal, insofar as feasible, HUD collects and reports data on race, ethnicity, gender, and income, and other characteristics of underrepresented and underserved communities relevant for research and analysis efforts.

HUD also encourages research to engage studied populations. ''Engagement'' means the deliberate and intentional inclusion of the thoughts and perspectives of studied groups, such as program participants, grantees, and underrepresented and underserved populations. This includes collecting people's thoughts and perspectives through standard (valid and rigorous) research methods such as surveys, focus groups, in-depth interviews, or ethnography to produce published research that conveys studied populations' thoughts and perspectives. In another type of engagement, people influence the research that is about them. This includes a wide range of activities that lie on a continuum from simple input (which should be documented and published) to full co-creation of any aspect of the research, from topic selection to research design, data collection, data analysis, interpretation, writing, or dissemination, or even being on the research team. An example of simple input is to include in the final report a summary of comments on the research by members of studied groups. Examples of collaboration include, but are not limited to, co-creating the list of topics to be covered in a survey or having members of a studied group on the research team.

To raise awareness of and spur creative approaches to engagement of studied populations in program evaluations and HUD-sponsored research, HUD may require contractors and grantees to explain how their research will and will not engage studied populations. HUD recognizes that engagement must be tailored to particular research efforts.

HUD retains the right to determine research methods.

HUD disseminates findings in ways that are accessible and useful to policymakers, practitioners, and members of communities affected by HUD programs and policies. Published findings will be accessible to individuals with disabilities pursuant to Section 508 of the Rehabilitation Act. PD&R partners with other HUD program offices to inform internal and external stakeholders through disseminating

evidence from HUD-sponsored evaluations.

Transparency

HUD will release methodologically valid evaluations without regard to the findings. Evaluation reports must describe the methods used, including strengths and weaknesses, and discuss the generalizability of the findings. Evaluation reports must present comprehensive results, including favorable, unfavorable, and null findings. HUD will publish interim findings, as projected in the initial research design. If there are indications that the findings of the final report may differ, HUD will provide appropriate qualifications accompanying the publication to guard against misunderstanding or misuse of the interim findings. If there are interim findings, HUD will publish those findings even if there are indications that the findings of the final report may differ. When findings are highly relevant to current policy, HUD evaluations carry a foreword articulating the policy position of the Department with respect to those findings.

If the findings of a HUD evaluation will have broad public interest and includes a counterfactual, PD&R will publish a synopsis of the research design, data collection and analysis plan soon after it is approved and will require interim and final reports that deviate from that document to explain how they deviate and why.

HUD publishes a 5-year Learning Agenda [4] that outlines the research and evaluation that it believes would be of greatest value to public policy. PD&R lists all ongoing evaluation projects at the HUDUSER.gov website [5] and updates it quarterly. PD&R will release evaluation results timely, usually within 4 months of receiving the final report.

HUD will, where possible, archive administrative and evaluation data for secondary use by interested researchers. HUD typically builds requirements into contracts to prepare data sets for secondary use. Access for external researchers may be provided directly through data licenses or indirectly through inter-agency agreements. This policy may not apply for data that has obvious commercial value, such as mortgage performance data. HUD staff may publish the results of their scholarship and analysis in any forum, so long as they do not claim to speak for the Department.

HUD evaluation contracts will generally permit contractors to publish their findings within 6 months of the termination of the contract if HUD has not already published them.

Independence

Independence and objectivity are core principles of evaluation. Agency and program leadership, program staff, service providers, and others participate actively in setting evaluation priorities, identifying evaluation questions, and assessing the implications of findings. However, it is important to insulate evaluation functions from undue influence and from both the appearance and the reality of bias. To promote objectivity, HUD protects independence in the design, conduct, and analysis of evaluations. To this end:

- HUD conducts evaluations through the competitive award of grants and contracts to external experts who are free from conflicts of interest.
- HUD also conducts evaluations in-house and supports unsolicited external evaluation proposals with funding, data, or both.
- The Evaluation Officer will consult with the HUD office with lead responsibility on the design of evaluation projects and analysis plans and will advise that office on whether to publish evaluation reports.

Ethics

HUD-sponsored evaluations must be conducted in an ethical manner and safeguard the dignity, rights, safety, and privacy of participants. HUD-sponsored evaluations must comply with both the spirit and the letter of relevant requirements such as regulations governing research involving human subjects. In particular, PD&R protects the privacy of HUD-assisted households and HUD-insured borrowers through its Rule of Eleven; that is, PD&R allows no disclosure of information about the characteristics of any group of individuals or households numbering fewer than eleven by PD&R staff, contractors, grantees, or licensees.

HUD is a signatory to the Federal Policy for the Protection of Human Subjects, generally known as the ''Common Rule.'' 24 CFR part 60, which includes its own requirements for ensuring adequate provisions to protect the privacy of human subjects research.[6]

HUD does not tolerate plagiarism, or fabrication or deliberate mischaracterization of data by staff, contractors or grantees who are engaged in evaluation activity.

Technical Innovation

PD&R supports and employs new methods of data collection and analysis that more reliably and efficiently answer research questions than old methods do.

Application of These Principles to Economic Analysis of Regulations

Economic analysis of both existing and proposed regulations, properly conducted, is a critical tool in improving public policy. Economists at HUD rely on the insights, data, and empirical estimates from rigorous program evaluations when predicting the economic impact of an incremental change to the program. In any HUD Regulatory Impact Analysis:

- HUD analyzes whether the issues addressed by the regulation stem from a market failure, government failure, or other systemic problem, and whether the regulation addresses the root causes of those problems.
- HUD uses and as necessary produces the best objective estimates of the benefits, costs, and transfers resulting from the regulation, taking into account gaps and uncertainties in the available data and methodologies.
- HUD assesses the economic benefits, costs, and transfers of proposed regulatory actions as required by Executive Order 12866.[7] HUD provides additional analysis of impacts across groups defined by race, ethnicity, and other characteristics that may define underrepresented and underserved groups when such analyses are relevant and feasible.
- Where clear alternatives to the regulatory actions exist, HUD objectively estimates the benefits, costs, and transfers of those alternatives, and additional analysis of impacts of those alternatives across underrepresented or underserved groups as well.

Todd M. Richardson,

Evaluation Officer.

[FR Doc. 2021–17339 Filed 8–12–21; 8:45 am]

BILLING CODE 4210–67–P

[4] *https://www.huduser.gov/portal/about/pdr_learningagenda.html.*

[5] *https://www.huduser.gov/portal/about/PDR-Research.html.*

[6] *https://www.ecfr.gov/cgi-bin/retrieveECFR?n=pt24.1.60.*

[7] See *https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf* for the original order, and see *https://www.archives.gov/federal-register/executive-orders/1993-clinton.html* for citations of, and links to, other executive orders that amended or supplemented this order.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7038–N–12; OMB Control No.: 2502–0598]

60-Day Notice of Proposed Information Collection: HUD Multifamily Rental Project Closing Documents

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 12, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of the documents referenced in this notice along with a summary of noteworthy changes may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: HUD Multifamily Rental Project Closing Documents.

OMB Approval Number: 2502–0598.

OMB Expiration Date: 4/30/2024.

Type of Request: Revision of currently approved collection.

Form Number: HUD–91070M, HUD–91071M, HUD–91073M, HUD–91710M, HUD–91712M, HUD–91725M, HUD–91725M–CERT, HUD–91725M–INST, HUD–92023M, HUD–92070M, HUD–92223M, HUD–92408M, HUD–92412M, HUD–92414M, HUD–92434M, HUD–92441M, HUD–92442M, HUD–92450M, HUD–92452A–M, HUD–92452M, HUD–92455M, HUD–92456M, HUD–92464M, HUD–92466M, HUD–92476.M, HUD–92476a–M, HUD–92476.1M, HUD–92477M, HUD–92478M, HUD–92479M, HUD–92554M, HUD–93305M, HUD–94000M, HUD–94001M, HUD–92907M, HUD–92908M.

Description of the need for the information and proposed use:

This information collection consists of numerous existing closing forms (Closing Documents) used in FHA-insured multifamily transactions.

HUD is also adding to the collection of Closing Documents twelve (12) documents, published, or referenced in Chapter 19 of the 2020 MAP Guide, 4430.G. The sample forms are not new. They were previous used in the Federal Housing Administration Multifamily Program Closing Guide, 4300.G, or available on HUD's website as sample forms. HUD will assign form numbers to each document upon PRA approval. Once published, preparers will use the OMB-approved forms and discontinue use of the ''sample'' documents. The following is a list of the names of the former ''sample'' documents that will receive HUD Form numbers.

List of New Forms:

9xxxM Borrower's Organizational Document Provisions, 9xxxM Building Code Verification, 9xxxM Certification of Architectural-Engineering Fees, 9xxxM Equity Bridge Loan Rider—LIHTC, 9xxxM Rider to Regulatory Agreement—Residual Receipts, 9xxxM Rider to Regulatory Agreement—Section 213, 9xxxM Rider to Security Instrument—Fee Joinder, 9xxxM Rider to Security Instrument—LIHTC Projects, 9xxxM Rider-Amendment to Restrictive Covenants, 9xxxM Survey Affidavit of No Change, 9xxxM Third Party Obligee Certification.

Respondents: FHA lenders, borrowers, housing finance agencies and other government agencies that support affordable housing, and HFA counsel.

Estimated Number of Respondents: 34,484.

Estimated Number of Responses: 34,484.

Frequency of Response: Once per annum.

Average Hours per Response: 1 hour.

Total Estimated Burden: 27,983.35.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Janet M. Golrick,

Acting, Chief of Staff for the Office of Housing—Federal Housing Administration.

[FR Doc. 2021–17327 Filed 8–12–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[212A2100DD AAK6006201 AOR3030.999900]

Indian Child Welfare Act (ICWA) Grants to Indian Organizations for Off-Reservation Indian Child and Family Service Programs

AGENCY: Office of Indian Services, Bureau of Indian Affairs, Interior.

ACTION: Solicitation of proposals; extension of deadline and updates to solicitation.

SUMMARY: The Secretary of the Interior (Secretary), through the Bureau of Indian Affairs (BIA), is soliciting grant proposals from Indian Organizations to establish and operate off-reservation Indian child and family service programs. The intent of the Indian child

and family service programs are to provide services for stabilizing Indian families and Tribes, preventing the breakup of Indian families and, in particular, to ensure that the permanent removal of an Indian child from the custody of his/her Indian parent or Indian custodian shall be a last resort. This notice updates the original solicitation to extend the application deadline, raise the award ceiling, and remove a restriction on the number of applications per applicant.

DATES: Grant application packages must be submitted no later than 5 p.m. Eastern Daylight Time, August 13, 2021. The BIA will not consider proposals received after this time and date.

ADDRESSES: Grant application packages must be submitted through *Grants.gov*. For information on how to apply for grants in *Grants.gov*, see the instructions available at: *https://www.grants.gov/help/html/help/Applicants/HowToApplyForGrants.htm*.

FOR FURTHER INFORMATION CONTACT: If you have questions regarding the application process, please contact Jo Ann Metcalfe, Grant Officer, via email at *jo.metcalfe@bia.gov* or phone at (703) 390–6410.

SUPPLEMENTARY INFORMATION: On June 23, 2021, BIA published in the **Federal Register** a solicitation for grant proposals from Indian Organizations to establish and operate off-reservation Indian child and family service programs. *See* 86 FR 32970. Today's notice makes several changes to that original solicitation. Specifically, this notice:

- Extends the July 16, 2021, proposal deadline to August 13, 2021;
- Raises the award ceiling from $100,000 per budget period to $200,000 per budget period; and
- Removes the restriction on an applicant submitting more than one application or being the beneficiary of more than one grant, to allow an applicant to submit more than one application and receive more than one grant under this notice as long as the proposals are for different services offered by the applicant organization.

All remaining provisions of the original solicitation remain in effect. *See* 86 FR 32970 (June 23, 2021).

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–17376 Filed 8–12–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORW00000.10200000. DF0000.LXSSH1080000.20X. HAG 21–0063]

Notice of Public Meeting for the San Juan Islands National Monument Advisory Committee, Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act, the Federal Advisory Committee Act of 1972, and the U.S. Department of the Interior, Bureau of Land Management (BLM), the San Juan Islands National Monument Advisory Committee (MAC) will meet as indicated below.

DATES: The MAC will hold a public meeting on Tuesday, September 14, 2021. This meeting will be held from 9:00 a.m. to 3:30 p.m. A public comment period will be available in the afternoon from 12 p.m. until 1 p.m.

ADDRESSES: The meeting will be held at the Lopez Community Center for the Arts, 204 Village Road, Lopez Island, WA 98261. There will be an option to participate in the meeting virtually as well. Virtual participation information will be posted online two weeks in advance of each meeting at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/oregon-washington/san-juan-islands-mac.*

FOR FURTHER INFORMATION CONTACT: Jeff Clark, Spokane District Public Affairs Officer, 1103 N. Fancher, Spokane Valley, WA 99212, telephone: (509) 536–1297, or email: *jeffclark@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1(800) 877–8339 to contact Mr. Clark during normal business hours. This service is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The San Juan Islands MAC is comprised of 12 members representing a wide array of interests, including recreation, Tribal interests, education, environmental organizations, and private landowners.

The meeting will begin at 9:00 a.m. with a welcome and agenda review. Members will then review the San Juan Islands National Monument Proposed Resource Management Plan and Environmental Impact Statement and clarifying items from the BLM. This discussion and review will continue until a working lunch at noon. At noon, members of the public will have the opportunity to make comments to the MAC during a 1-hour public comment period. The review will continue after the public comment period, if necessary. The next topic will be to consider opportunities for the MAC to support implementation of the management plan once the record of decision is signed. The MAC will adjourn no later than 3:30 p.m.

All MAC meetings are open to the public. Persons wishing to make comments during the public comment period should register in person with the BLM by 11:00 a.m. on the meeting day. Depending on the number of persons wishing to speak and the time available, the amount of time or oral comments may be limited. Written public comments may be sent to the BLM Spokane District office listed in the **ADDRESSES** section of this notice. All comments received will be provided to the MAC.

(Authority: 43 CFR 1784.4–2)

Kurt Pindel,

Spokane District Manager.

[FR Doc. 2021–17322 Filed 8–12–21; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[212.LLHQ230000.L11700000.PI0000. LXSGCO000000]

Notice to Re-Initiate Proposed Withdrawal; Sagebrush Focal Areas

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of re-initiation.

SUMMARY: In compliance with an Order from the United States District Court for the District of Idaho (the Court), this notice announces that the Secretary of the Interior is re-initiating consideration of the September 24, 2015, proposal by the Assistant Secretary for Land and Minerals Management, as amended on December 30, 2016, to withdraw approximately 10 million acres of public and National Forest System lands from location and entry under the United States mining laws to protect the Greater Sage-Grouse and its habitat, subject to valid existing rights. The lands included in this proposal are referred to as Sagebrush Focal Areas (SFAs). The Bureau of Land Management (BLM) had previously canceled the withdrawal application. The Court vacated cancellation of the withdrawal application and proposal and remanded to the BLM for further

proceedings and consideration of whether the withdrawal is needed for sage grouse conservation. Accordingly, this notice announces that the BLM is now re-initiating the National Environmental Policy Act (NEPA) process to inform the Secretary's consideration of whether to withdraw any of the lands proposed for withdrawal. This notice does not segregate any of the lands described in the proposal, which, subject to any overlapping withdrawals, remain open to location and entry under the mining laws.

DATES: The BLM will shortly issue a new draft Environmental Impact Statement (EIS) and publish a Notice of Availability (NOA) initiating a public comment period.

FOR FURTHER INFORMATION CONTACT: Patricia Deibert, National Sage-grouse Coordinator (Acting), BLM Headquarters, at email: *blm_hq_sfa_withdrawal@blm.gov;* telephone: 307–757–3709. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Ms. Seibert during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: On September 24, 2015, a Notice of Proposed Withdrawal was published in the **Federal Register** (80 FR 57635), as corrected (80 FR 63583), which provided notice of the proposal to withdraw approximately 10 million acres of Federal lands in Idaho, Montana, Nevada, Oregon, Utah, and Wyoming from location and entry under the United States mining laws for 20 years, subject to valid existing rights. The lands included in the proposed action are National System of Public Lands and National Forest System lands administered by the BLM and the United States Forest Service (USFS). The BLM is the agency lead for this proposed withdrawal.

On December 30, 2016, a Notice of Amended Proposed Withdrawal, Release of Draft Environmental Impact Statement, and Notice of Public Meetings; Idaho, Montana, Nevada, Oregon, Utah, and Wyoming was published in the **Federal Register** (81 FR 96478). The amended proposal added 387,981.42 acres in the State of Nevada and proposed boundary refinements in Idaho, Montana, Nevada, Oregon, Utah, and Wyoming that were identified because of legal land description refinements. The notice released for public comment a draft EIS, which analyzed and disclosed the impacts of the proposed withdrawal. The notice included a summary of scoping comments, the issues analyzed, and the alternatives considered in the draft EIS. The draft EIS can be found on BLM's National NEPA Register at *https://eplanning.blm.gov/eplanning-ui/project/70697/510 (DOI-BLM-WO-WO3500-2016-0002-EIS).* The BLM sought comments on the draft EIS from December 30, 2016, through March 28, 2017. The BLM received approximately 4,200 comment submissions on the draft EIS, of which approximately 192 submissions were unique.

A Notice of Cancellation of Withdrawal Application and Withdrawal Proposal and Notice of Termination of Environmental Impact Statement was published on October 11, 2017, in the **Federal Register** (82 FR 47248), which stated that the BLM had determined the lands were no longer needed in connection with the proposed withdrawal, and terminated the preparation of an EIS evaluating the application and proposal. The BLM canceled the application prior to responding to public comments and publishing a final EIS.

The cancellation was then vacated by the Court on February 11, 2021 (Western Watersheds Project v. Bernhardt, Case No. 1:16–cv–00083–BLW, EFC 264). The Court ordered the BLM to consider ''whether the withdrawal is needed for sage-grouse conservation,'' and that ''[s]ich proceedings shall include re-initiation of the NEPA process.''

To comply with the Court's order and to review issues raised during the initial scoping and comment period for the draft EIS published on December 30, 2016, the BLM will issue a new draft EIS and publish an NOA initiating a public comment period. The withdrawal proposal will continue to be processed in accordance with the regulations set forth in 43 CFR part 2300. The process will inform a final decision as to whether to withdraw any of the lands proposed for withdrawal from location and entry under the mining laws. This notice does not segregate the lands because the segregation period for this withdrawal proposal expired on September 24, 2017. All the lands (unless subject to an existing withdrawal) remain open to location and entry under the mining laws.

The lands included in the withdrawal application were published in the previous notices. A description of the lands is posted on BLM's National NEPA Register at *https://eplanning.blm.gov/eplanning-ui/project/70697/510 (DOI-BLM-WO-WO3500-2016-0002-EIS).* Non-Federal mineral lands located within the boundaries of the proposed withdrawal areas will not be affected.

Thirty-one agencies and two American Indian Tribes entered into cooperating agency agreements with the BLM for the EIS process. The BLM will re-initiate participation with cooperating agencies for this NEPA process.

The BLM also contacted 53 American Indian governments via letter or face-to-face meetings during scoping and prior to the release of the draft EIS. The governments were provided a project update, an offer to provide more information, and an offer for government-to-government consultation. The BLM will re-initiate consultation with Indian tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies for this NEPA process.

In accordance with 36 CFR 800.3(a)(1), the BLM previously determined that the proposed SFA withdrawal is an undertaking that has no potential to affect historic properties, assuming such historic properties were present, and therefore the agency official has no further obligation under the National Historic Preservation Act. The BLM informed 53 American Indian governments; the Idaho, Montana, Nevada, Oregon, Utah, and Wyoming State Historic Preservation Offices; and the Advisory Council on Historic Preservation of this determination of effect. This previous determination by the BLM remains accurate and will not be changed during re-initiated consideration of the withdrawal proposal.

David Jenkins,

Assistant Director, Resources and Planning.

[FR Doc. 2021–17359 Filed 8–12–21; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–CEBE–32227; PPNECEBE00, PPMPSAS1Z.Y00000]

Cedar Creek and Grove National Historical Park Advisory Commission Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service is hereby giving notice that the Cedar Creek and Belle Grove National

Historical Park Advisory Commission (Commission) will meet as indicated below.

DATES: The meeting will be held on Thursday, September 16, 2021, from 9:00 a.m. to 11:00 a.m. (EASTERN).

ADDRESSES: The meeting will be held in the Middletown Town Hall Council Chambers, 7875 Church Street, Middletown, VA 22645. Enter through the rear of the building which leads directly into the council chambers. A teleconference may substitute for an in-person meeting if public health restrictions are in effect. Additional information will be made available on the Park's website: *https://www.nps.gov/cebe/index.htm.*

FOR FURTHER INFORMATION CONTACT: Karen Beck-Herzog, Site Manager, Cedar Creek and Belle Grove National Historical Park, P.O. Box 700, Middletown, Virginia 22645, telephone (540) 868–9176, or visit the park website: *https://www.nps.gov/cebe/index.htm.*

SUPPLEMENTARY INFORMATION: The Commission was designated by Congress to provide advice to the Secretary of the Interior on the preparation and implementation of the park's general management plan and to advise on land protection (16 U.S.C. 410iii–7). Individuals who are interested in the park, the implantation of the plan, or the business of the Commission are encouraged to attend the meeting. This meeting is open to the public. Interested members of the public may present, either orally or through written comments, information for the Commission to consider during the public meeting. Attendees and those wishing to provide comment are strongly encouraged to preregister through the contact information provided. A detailed final agenda will be posted 48 hours in advance of the meeting on the Commission's website at *https://www.nps.gov/cebe/learn/management/park-advisory-commission.htm.*

Purpose of the Meeting: The topics to be discussed include: general management plan next steps, visitor services and interpretation, land protection planning, historic preservation, and natural resource protection.

Commission meetings consist of the following:

1. General Introductions
2. Review and Approval of Commission Meeting Notes
3. Reports and Discussions
4. Old Business
5. New Business
6. Public Comments
7. Closing Remarks

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

(Authority: 5 U.S.C. Appendix 2)

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2021–17366 Filed 8–12–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–GATE–31982; PPNEGATEB0, PPMVSCS1Z.Y00000]

Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee; Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service (NPS) is hereby giving notice that the Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee (Committee) will meet as indicated below.

DATES: The virtual meeting will take place on Thursday, September 23, 2021. The meeting will begin at 9:00 a.m. until 1:30 p.m., with a public comment period at 11:15 a.m. to 12:00 p.m. (EASTERN). Please contact Daphne Yun (see **FOR FURTHER INFORMATION CONTACT**) no later than September 21, 2021, to receive instructions for accessing the meeting.

FOR FURTHER INFORMATION CONTACT: This will be a virtual meeting. Anyone interested in attending or submitting a public comment should contact Daphne Yun, Acting Public Affairs Officer, Gateway National Recreation Area, 210 New York Avenue, Staten Island, New York 10305, or by telephone (718) 815–3651, or by email *daphne_yun@nps.gov.*

SUPPLEMENTARY INFORMATION: The Committee was established on April 18, 2012, by authority of the Secretary of the Interior (Secretary) under 54 U.S.C. 100906, and is regulated by the Federal Advisory Committee Act. The Committee provides advice to the Secretary, through the Director of the NPS, on matters relating to the Fort Hancock Historic District of Gateway National Recreation Area. All meetings are open to the public.

Purpose of the Meeting: The Gateway National Recreation Area will discuss park and leasing updates, updates from working groups, including an update on the Stillman proposal. The final agenda will be posted on the Committee's website at *https://www.forthancock21.org.* The website includes meeting minutes from all prior meetings.

Interested persons may present, either orally or through written comments, information for the Committee to consider during the public meeting. Written comments will be accepted prior to, during, or after the meeting. Members of the public may submit written comments for consideration by the Committee to Daphne Yun (see **FOR FURTHER INFORMATION CONTACT**).

Due to time constraints during the meeting, the Committee is not able to read written public comments submitted into the record. Individuals or groups requesting to make oral comments at the public Committee meeting will be limited to no more than three minutes per speaker. All comments will be made part of the public record and will be electronically distributed to all Committee members. Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your written comments, you should be aware that your entire comment including your personal identifying information will be publicly available. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 5 U.S.C. Appendix 2)

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2021–17368 Filed 8–12–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–32168; PPWOCRAD10, PUC00RP14.R50000]

Cold War Advisory Committee Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: The National Park Service (NPS) is hereby giving notice that the Cold War Advisory Committee (Committee) will meet as indicated below.

DATES: The Committee will meet via GoToWebinar on Tuesday, September 14, 2021, from 2:00 p.m. until approximately 4:00 p.m. (Eastern).

FOR FURTHER INFORMATION CONTACT: Lisa P. Davidson, Ph.D., Acting Program Manager, National Historic Landmarks Program, Historian, Heritage Documentation Programs, National Park Service, telephone at (202) 354–2179, or email *lisa_davidson@nps.gov*. Teleconference participants may register for the meeting at the following url: *https://attendee.gotowebinar.com/register/5948428690832074256*.

After registering, participants will receive a confirmation email containing information about joining the teleconference. Participants may register at any time and will receive the login information immediately.

SUPPLEMENTARY INFORMATION: The Committee was established by title VII, subtitle C, section 7210 of the Omnibus Public Land Management Act of 2009 (16 U.S.C. 1a–5 note).

The Committee meeting will be open to the public and will have time allocated for public comment. Meeting minutes will be available upon request approximately eight weeks after the meeting.

Purpose of the Meeting: The Committee assists the Secretary of the Interior in the preparation of a national historic landmark theme study to identify sites and resources significant to the Cold War. The agenda may change to accommodate Committee business. The proposed meeting agenda includes the following:

1. Call to Order and Welcome
2. Welcome from the NPS
3. Introductions
4. Status Report—Mountain Home National Historic Landmarks Nomination and Cold War National Historic Landmarks Theme Study
5. Introduction of Draft Cold War Interpretive Handbook
6. Discussion of Cold War Interpretive Handbook
7. Public Comments
8. Adjourn Meeting

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 5 U.S.C. Appendix 2)

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2021–17367 Filed 8–12–21; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1248]

Certain Cellular Communications Infrastructure Systems, Components Thereof, and Products Containing Same; Commission Determination Not To Review an Initial Determination Terminating the Investigation in Its Entirety Based on Settlement; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 6) of the presiding administrative law judge (''ALJ''), terminating the investigation in its entirety based on settlement. This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov*. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on February 22, 2021, based on a complaint filed on behalf of Ericsson Inc. of Plano, Texas and Telefonaktiebolaget LM Ericsson of Sweden (collectively, ''Ericsson''). 86 FR 10596 (Feb. 22, 2021). The complaint, as amended, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain cellular communications infrastructure systems, components thereof, and products containing same by reason of infringement of certain claims of U.S. Patent Nos. 9,037,166; 9,107,082; 9,509,605; and 9,692,682. *Id.* The complaint also alleged that an industry in the United States exists as required by section 337. *Id.* The Commission's notice of investigation named as respondents Samsung Electronics Co. Ltd. of Republic of Korea and Samsung Electronics America, Inc. of Ridgefield Park, New Jersey (collectively, ''Samsung''). *Id.* The Office of Unfair Import Investigations is not participating in this investigation.

On July 13, 2021, Ericsson and Samsung jointly moved pursuant to 19 CFR 210.21(a)(2) and (b) to terminate the investigation based on a settlement agreement (''the Agreement''). The motion attached public and confidential versions of the Agreement.

On July 22, 2021, the ALJ issued Order No. 6, the subject ID, which granted the motion. The ID found that the motion complied with the Commission's Rules and that there are no extraordinary circumstances that warrant denying the motion. The ID also found that there is no evidence indicating that terminating this investigation would be contrary to the public interest. No petitions for review of the ID were received.

The Commission has determined not to review the subject ID. The investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on August 10, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 10, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–17370 Filed 8–12–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1526 (Final)]

Silicon Metal From Malaysia; Determination

On the basis of the record [1] developed in the subject investigation, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of silicon metal, provided for in subheadings 2804.69.10 and 2804.69.50 of the Harmonized Tariff Schedule of the United States, from Malaysia, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'').

Background

The Commission instituted the investigations effective June 30, 2020, following receipt of petitions filed with the Commission and Commerce by Globe Specialty Metal, Inc., Beverly, Ohio and Mississippi Silicon, LLC, Burnsville, Mississippi. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of silicon metal from Kazakhstan were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and that imports of silicon metal from Bosnia and Herzegovina and Iceland were being sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on December 30, 2020 (85 FR 86578). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission conducted its hearing through written testimony and video conference on February 22, 2021. All persons who requested the opportunity were permitted to participate.

The investigation schedules became staggered when Commerce: (i) Postponed the final determination for its antidumping duty investigation regarding Silicon Metal from Malaysia; and (ii) reached earlier final antidumping and countervailing duty determinations concerning Silicon Metal from Bosnia and Herzegovina, Iceland, and Kazakhstan. On April 12, 2021, the Commission issued final affirmative determinations in its antidumping and countervailing duty investigations of Silicon Metal from Bosnia and Herzegovina, Iceland, and Kazakhstan (86 FR 20197, April 16, 2021). Following notification of a final determination by Commerce that imports of Silicon Metal from Malaysia were being sold at LTFV within the meaning of section 735(a) of the Act (19 U.S.C. 1673d(a)),[2] notice of the supplemental scheduling of the final phase of the Commission's antidumping duty investigation with respect to Malaysia was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on June 30, 2021 (86 FR 34786).

The Commission made this determination pursuant to § 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determination in this investigation on August 9, 2021. The views of the Commission are contained in USITC Publication 5220 (August 2021), entitled *Silicon Metal from Malaysia: Investigation No. 731–TA–1526 (Final).*

By order of the Commission.

Issued: August 9, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–17308 Filed 8–12–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1275]

Certain Networking Devices, Computers, and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 1, 2021, under section 337 of the Tariff Act of 1930, as amended, on behalf of Proven Networks, LLC of Los Angeles, California. An amended complaint was filed on June 11, 2021, and a supplement to the amended complaint was filed on July 27, 2021. The amended complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain networking devices, computers, and components thereof by reason of infringement of certain claims of U.S. Patent No. 8,687,573 (''the '573 patent''). The amended complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, as amended and supplemented, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2020).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on August 10, 2021, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 86 FR 33224, June 24, 2021.

United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–37 of the '573 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''networking appliances, such as switches, gateways, and application delivery controller products, that manage the flow of traffic and bandwidth for application quality of service, policy management, and security over a network, and related software'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of institution of investigation shall be served:

(a) The complainant is: Proven Networks, LLC, 12424 Wilshire Blvd., 12th Floor, Los Angeles, CA 90025.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served: F5 Networks, Inc., 801 5th Ave., Seattle, WA 98104.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of institution of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of institution of investigation. Extensions of time for submitting responses to the complaint and the notice of institution of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: August 10, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–17372 Filed 8–12–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Video Security Equipment and Systems, Related Software, Components Thereof, and Products Containing Same, DN 3565;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Motorola Solutions, Inc.; Avigilon Corporation; Avigilon Fortress Corporation; Avigilon Patent Holding 1 Corporation; and Avigilon Technologies Corporation on August 9, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain video security equipment and systems, related software, components thereof, and products containing same. The complainant names as a respondent: Verkada Inc. of San Mateo, CA. The complainant requests that the Commission issue a limited exclusion order, a cease and desist order, and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3565'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: August 9, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–17303 Filed 8–12–21; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov*.

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1545 (Final)]

Utility Scale Wind Towers From Spain; Determination

On the basis of the record [1] developed in the subject investigation, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of utility scale wind towers (''wind towers'') from Spain, provided for in subheadings 7308.20.00 and 8502.31.00 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'').[2]

Background

The Commission instituted antidumping and countervailing duty investigations effective September 30, 2020, following receipt of petitions filed with the Commission and Commerce by the Wind Tower Trade Coalition (Arcosa Wind Towers Inc., Dallas, Texas; and Broadwind Towers, Inc., Manitowoc, Wisconsin). The Commission established a general schedule for the conduct of the final phase of its investigations on wind towers from India, Malaysia, and Spain following preliminary determinations by Commerce that imports of wind towers were subsidized by the governments of India and Malaysia. Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of April 16, 2021 (86 FR 20197). Counsel for the Wind Tower Trade Coalition withdrew its previously filed request to appear at the hearing, after no other parties submitted a request to appear, and indicated a willingness to submit written responses to any Commission questions in lieu of a hearing. Consequently, since no party to the proceeding requested a hearing, the Commission canceled its hearing in connection with this proceeding (86 FR 31730, June 9, 2021). Parties to this proceeding responded to written questions posed by the Commission in their posthearing briefs.

The investigation schedules became staggered when Commerce did not align its countervailing duty investigation with its antidumping duty investigation regarding imports from Malaysia (86 FR 27828, May 24, 2021), nor with its antidumping duty investigation regarding imports from Spain (86 FR 17373, Apr. 2, 2021), while it aligned its countervailing duty investigation regarding imports from India with that of its corresponding postponed antidumping duty investigation, and postponed its antidumping duty investigation regarding Malaysia (86 FR 15897, Mar. 25, 2021; 86 FR 38274, July 20, 2021; 86 FR 27828, May 24, 2021). On July 26, 2021, the Commission issued a final affirmative determination in its countervailing duty investigation of wind towers from Malaysia (86 FR 41087, July 30, 2021). Following notification of a final determination by Commerce that imports of wind towers from Spain were being sold at LTFV within the meaning of section 735(a) of the Act (19 U.S.C. 1673d(a)), notice of the supplemental scheduling of the final phase of the Commission's antidumping duty investigation regarding Spain was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission,

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 86 FR 33656, June 25, 2021.

Washington, DC, and by publishing the notice in the **Federal Register** of July 9, 2021 (86 FR 36305).

The Commission made this determination pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determination in this investigation on August 9, 2021. The views of the Commission are contained in USITC Publication 5219 (August 2021), entitled *Utility Scale Wind Towers from Spain: Investigation No. 731–TA–1545 (Final).*

By order of the Commission.

Issued: August 9, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–17309 Filed 8–12–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB 1140–0036]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Revision of a Currently Approved Collection; FFL Out of Business Records Request—ATF Form 5300.3A

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ) will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 1140–0036 (FFL Out of Business Records Request—ATF F 5300.3A) is being revised to include updated contact information, make minor changes in wording to improve form clarity, and identify an increase in the total burden hours since the last renewal in 2018. The proposed information collection is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until October 12, 2021.

FOR FURTHER INFORMATION CONTACT: If you have additional comments regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: Matthew S. Grim, Tracing Operations & Records Mgt. Branch, National Tracing Center Division either by mail at ATF National Services Center, 244 Needy Road, Martinsburg, WV 25405, by email at *matthew.grim@atf.gov,* or by telephone at 304–260–3683.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* FFL Out of Business Records Request.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 5300.3A.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other (if applicable): None.

Abstract: The FFL Out of Business Records Request—ATF Form 5300.3A is used to notify Federal firearms licensees (FFLs) who go out of business to submit their firearms records to the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) if the business discontinuance is absolute. FFLs can also use the form to notify ATF of a successor business that will maintain control of the firearms records.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* A combined 4,297 respondents will use the form and then package and ship/deliver business records to ATF following business discontinuance. It will take a combined total of 5 minutes for respondents to prepare the form and an additional 11 hours to package and then ship/deliver business records to ATF.

6. *An estimate of the total public burden (in hours) associated with the collection:* The combined estimated annual public burden associated with this collection is 47,523 hours, which is equal to 3,066 (# of respondents who completed the form) * 0.0833333 (5 minutes or the total time to complete each form) + 4,297 (# of respondents who ship/deliver records) *11 hours (time taken to package ship/deliver records to ATF).

7. *An Explanation of the Change in Estimates:* Since the last renewal in 2018, the total responses and mailing costs decreased from 4,607 to 4,297 and from $ 2,243,013 to $ 2,098,869 respectively, due to fewer FFLs going out of business. However, the total burden increased to 47,523 hours because it took each FFL more time to prepare an average 7 boxes of business records in 2020, compared to an estimated 4 boxes of records in 2018.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3E.405A, Washington, DC 20530.

Dated: August 9, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–17287 Filed 8–12–21; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–883]

Importer of Controlled Substances Application: Catalent CTS, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Catalent CTS, LLC. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 13, 2021. Such persons may also file a written request for a hearing on the application on or before September 13, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 9, 2021, Catalent CTS, LLC., 10245 Hickman Mills Drive, Kansas City, Missouri 64137–1418, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Marihuana Extract	7350	1
Marihuana	7360	1
Tetrahydrocannabinols	7370	I

The company plans to import the above controlled substances as dosage unit products for clinical trial studies. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2021–17310 Filed 8–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0012]

Agency Information Collection Activities; Proposed eCollection Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office on Violence Against Women (OVW), Department of Justice, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until October 12, 2021.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Education, Training and Enhanced Services to End Violence Against and Abuse of Women with Disabilities Grant Program (Disability Grant Program).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0012. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 18 grantees of the Disability Grant Program. Grantees include states, units of local government, Indian tribal governments or tribal organizations and non-governmental private organizations. The goal of this program is to build the capacity of such jurisdictions to address such violence against individuals with disabilities through the creation of multi-disciplinary teams. Disability Grant Program recipients will provide training, consultation, and information on domestic violence, dating violence, stalking, and sexual assault against individuals with disabilities and enhance direct services to such individuals.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 18 respondents (Disability Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Disability Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 36 hours, that is 18 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required, contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: August 9, 2021.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2021–17286 Filed 8–12–21; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Partial Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

On August 7, 2021, the Department of Justice lodged a proposed Partial Consent Decree Regarding Certain Cost Claims (''Consent Decree'') in the United States District Court for the Central District of California, in the lawsuit entitled the *United States of America and State of California* v. *Shell Oil Company, et al.,* Civil Action No. 2:91–CV–00589 (CJC).

This Consent Decree represents a settlement of certain cost claims of the United States (''Plaintiff'') against Shell Oil Company, (''Shell'' or ''Defendant'') under Sections 106, 107, and 113 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9606, 9607, and 9613, relating to the McColl Superfund Site in Fullerton, California. Under the proposed Consent Decree, Shell will be required to pay the United States $29,501,511.85, plus interest in the amount of $3,059.39, and $75.83 per day from 3/16/2021 through the date of payment. Shell is also required under the Consent Decree to pay its allocated fair share of future response costs.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America* v. *Shell Oil Company, et al,* and the D.J. Ref. No. 90–11–2–3A. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Amended Consent Decree may be examined and downloaded at this Justice Department website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $6.25 (25 cents per page reproduction cost) payable to the United States Treasury for the Consent Decree and $20.00 for the Consent Decree and Appendices thereto.

Lori Jonas,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–17281 Filed 8–12–21; 8:45 am]

BILLING CODE 4410–CW–P

DEPARTMENT OF JUSTICE

[OMB Control No. 1103–NEW]

Information Collection; Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)

AGENCY: Office of the Chief Information Officer, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice as part of its continuing effort to reduce paperwork and respondent burden, is announcing an opportunity for public comment on a new proposed collection of information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 30 days for public comment in response to the notice. This notice solicits comments on new collection proposed by the Agency.

DATES: Submit comments on or before: September 13, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

A. Purpose

Under the PRA, (44 U.S.C. 3501–3520) Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, GSA is publishing notice of the proposed collection of information set forth in this document.

Whether seeking a loan, Social Security benefits, veteran's benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector.

A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: Conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. The De will limit its inquiries to data collections that solicit strictly

voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on *performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

Method of Collection

The Department will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. The Department may also utilize observational techniques to collect this information.

Data

Form Number(s): None.
Type of Review: New.

B. Annual Reporting Burden

Affected Public: Collections will be targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future. For the purposes of this request, ''customers'' are individuals, businesses, and organizations that interact with a Federal Government agency or program, either directly or via a Federal contractor. This could include individuals or households; businesses or other for-profit organizations; not-for-profit institutions; State, local or tribal governments; Federal government; and Universities.

Estimated Number of Respondents: 2,001,550.

Estimated Time per Response: Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 1.5 hours to participate in an interview.

Estimated Total Annual Burden Hours: 101,125.

Estimated Total Annual Cost to Public: $0.

C. Public Comments

The Department invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 10, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–17386 Filed 8–12–21; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection; Correction

AGENCY: Office of Violence Against Women, Department of Justice.

ACTION: Notice; correction.

SUMMARY: The Office of Violence Against Women, Department of Justice, submitted two notices for publication in the **Federal Register** on July 30, 2021 soliciting comments to an information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The document contained incorrect information.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.gov.*

SUPPLEMENTARY INFORMATION: *Corrections:* In the **Federal Register** of July 30, 2021, in FR Doc. 2021–16313, on page 41093, in the second column, correct the **ACTION** caption to read: 30-Day notice and correct the **DATES** caption to read: Comments are encouraged and will be accepted for 30 days until August 30, 2021.

In the **Federal Register** of July 30, 2021, in FR Doc. 2021–16312, on page 41094, in the third column, correct the **ACTION** caption to read: 30-Day notice and correct the **DATES** caption to read: Comments are encouraged and will be accepted for 30 days until August 30, 2021.

Dated: August 9, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–17297 Filed 8–12–21; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0016]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until September 13, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision to Currently Approved Collection.

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Grantees of the Transitional Housing Assistance Grant Program.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0016. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 120 grantees of the Transitional Housing Assistance Grant Program (Transitional Housing Program) whose eligibility is determined by statute. This discretionary grant program provides transitional housing, short-term housing assistance, and related support services for individuals who are homeless, or in need of transitional housing or other housing assistance, as a result of fleeing a situation of domestic violence, dating violence, sexual assault, or stalking, and for whom emergency shelter services or other crisis intervention services are unavailable or insufficient. Eligible applicants are States, units of local government, Indian tribal governments, and other organizations, including domestic violence and sexual assault victim services providers, domestic violence or sexual assault coalitions, other nonprofit, nongovernmental organizations, or community-based and culturally specific organizations, that have a documented history of effective work concerning domestic violence, dating violence, sexual assault, or stalking.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the 120 respondents (grantees) approximately one hour to complete the Semi-Annual Progress Report. The semi-annual progress report is divided into sections that pertain to the different types of activities that grantees may engage in and the different types of grantees that receive funds. A Transitional Housing Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 240 hours, that is 120 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: August 9, 2021.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2021–17298 Filed 8–12–21; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0007]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Office on Violence Against Women (OWW), Department of Justice, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until October 12, 2021.

FOR FURTHER INFORMATION CONTACT: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Grantees of the Legal Assistance for Victims Grant Program.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0007. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 200 grantees of the Legal Assistance for Victims Grant Program (LAV Program) whose eligibility is determined by statute. In 1998, Congress appropriated funding to provide civil legal assistance to domestic violence victims through a set-aside under the Grants to Combat Violence Against Women, Public Law 105–277. In the Violence Against Women Act of 2000 and again in 2005, Congress statutorily authorized the LAV Program. 34 U.S.C. 20121. The LAV Program is intended to increase the availability of legal assistance necessary to provide effective aid to victims of domestic violence, stalking, or sexual assault who are seeking relief in legal matters arising as a consequence of that abuse or violence. The LAV Program awards grants to law school legal clinics, legal aid or legal services programs, domestic violence victims' shelters, bar associations, sexual assault programs, private nonprofit entities, and

Indian tribal governments. These grants are for providing direct legal services to victims of domestic violence, sexual assault, and stalking in matters arising from the abuse or violence and for providing enhanced training for lawyers representing these victims. The goal of the Program is to develop innovative, collaborative projects that provide quality representation to victims of domestic violence, sexual assault, and stalking.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 200 respondents (LAV Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities that grantees may engage in and the different types of grantees that receive funds. An LAV Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 400 hours, that is 200 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: August 9, 2021.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2021–17299 Filed 8–12–21; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Vertical Tandem Lifts for Marine Terminals

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety and Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 13, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie by telephone at 202–693–0456 or by email at *DOL_PRA_PUBLIC@dol.gov*.

SUPPLEMENTARY INFORMATION: The Vertical Tandem Lifts (VTLs) Standard requires employers to develop, implement, and maintain a written plan for transporting vertically connected containers in the longshoring and marine terminal industries. The written plan is necessary for the safe transport of VTLs in the marine terminal where factors affect the stability of a VTL which has a higher center of gravity than a single container. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 3, 2021 (86 FR 23432).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Vertical Tandem Lifts Marine Terminals.

OMB Control Number: 1218–0260.

Affected Public: Private Sector: Businesses or other for-profits.

Total Estimated Number of Respondents: 1,192.

Total Estimated Number of Responses: 75,875.

Total Estimated Annual Time Burden: 23,256 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Crystal Rennie,

Senior PRA Analyst.

[FR Doc. 2021–17335 Filed 8–12–21; 8:45 am]

BILLING CODE 4510–26–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 21–06]

Notice of First Amendment to Compact With the Republic of Benin

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: In accordance with the Millennium Challenge Act of 2003, as amended, the Millennium Challenge Corporation is publishing a summary, justification, and full text of the proposed First Amendment to Millennium Challenge Compact between the United States of America, acting through the Millennium Challenge Corporation, and the Republic of Benin. Representatives of the United States Government and the Government of Benin plan to conclude the Amendment in August 2021.

(Authority: 22 U.S.C. 7708(i)(2))

Dated: August 3, 2021.

Thomas G. Hohenthaner,

Acting VP/General Counsel and Corporate Secretary.

Summary of First Amendment to Millennium Challenge Compact With the Republic of Benin

The Board of Directors of the Millennium Challenge Corporation

(''*MCC*'') has approved an amendment (the ''*Amendment*'') to the existing US$375,000,000, five-year Millennium Challenge Compact between the United States of America, acting through MCC, and the Republic of Benin (the ''*Compact*'').

Background

The Compact was signed September 9, 2015 and entered into force on June 22, 2017. The Compact aims to strengthen Benin's national power utility, attract private sector investment into solar power generation, and fund infrastructure investments in electricity distribution as well as off-grid electrification for poor and unserved households. The Compact comprises four projects: The Policy Reform and Institutional Strengthening Project, the Electricity Generation Project, the Electricity Distribution Project, and the Off-Grid Electricity Access Project.

Scope of the Amendment

MCC proposes to extend the term of the Compact for an additional twelve months to June 22, 2023, and to provide additional funding up to $16,000,000. The term extension is necessary to mitigate implementation delays due to the COVID–19 pandemic and to complete infrastructure projects as originally contemplated. The proposed additional funding will be used to cover additional program administration and related oversight costs associated with extending the Compact's term.

Justification for the Amendment

In March 2020, Benin registered its first COVID–19 case, and within a week, the Government of Benin imposed compulsory 14-day quarantine requirements for air travelers, closed land borders to all but emergency travel, restricted visa issuance, and limited movement outside of the major population centers in southern Benin, cutting off access to the economic and political capitals from the rest of the country.

Contractors for the six major works packages that comprise nearly half of the compact budget rapidly imposed telework requirements and restrictions on staff travel, and shortly thereafter commercial airlines stopped servicing Benin. While contractors attempted to mitigate the impact of international travel restrictions by using local hires and consultants, domestic travel restrictions effectively prevented travel to 97% of the Benin's territory. The net effect of these developments was to hinder mobilization of contractor key staff to Benin and deployment of field staff to work sites, resulting in delays in field surveys, equipment imports, hiring of sub-contractors, and setting up offices and construction material warehouses. These mobilization delays in turn had a knock-on effect on the completion of final construction designs, field surveys, drawings, and management plans, and subsequent start of civil works. Outside of Benin, imposition of COVID–19 mitigation measures led to equipment manufacturing and shipping delays, thereby slowing contractor procurements, factory testing and acceptance of key substation components, the delivery of materials to site, and equipment installation at project work sites.

Extending the Compact's term will maximize long-term results and the return on investment by enabling MCC and the accountable entity in Benin to complete and hand over all ongoing projects to the beneficiary institutions without compromising health, safety, or environmental standards, and will reduce sustainability risks through the necessary attention to testing, commissioning, training of utility operators and technicians, and additional oversight. The additional MCC funding is necessary for and will be used to support oversight and other administrative functions during the additional twelve months of the compact term.

First Amendment to Millennium Challenge Compact Between the United States of America, Acting Through the Millennium Challenge Corporation and the Republic of Benin

First Amendment to Millennium Challenge Compact

This First Amendment to Millennium Challenge Compact (this ''*Amendment*''), is made by and between the United States of America, acting through the Millennium Challenge Corporation, a United States government corporation (''*MCC*''), and the Republic of Benin, acting through its government (the ''*Government*'') (each referred to herein individually as a ''*Party*'' and collectively, as the ''*Parties*''). All capitalized terms used in this Amendment that are not otherwise defined herein have the meanings given to such terms in the Compact (as defined below).

Recitals

Whereas, the Parties signed that certain Millennium Challenge Compact by and between the United States of America, acting through MCC, and the Republic of Benin, on September 9, 2015 (as modified, the ''*Compact*'');

Whereas, Section 7.4 of the Compact provides for a Compact Term of five (5) years after its entry into force;

Whereas, the Compact entered into force on June 22, 2017;

Whereas, implementation of the Program has been adversely affected and delayed by the coronavirus pandemic;

Whereas, the Parties now desire to extend the Compact Term by an additional twelve (12) months (the ''*Extension*''), and to increase MCC's assistance under the Compact for related administrative and oversight costs, to allow the Government more time to implement and complete the Projects in order to fully achieve the Compact Goal, Program Objective and Project Objectives; and

Whereas, pursuant to Section 6.2(a) of the Compact, the Parties desire to amend the Compact as more fully described herein to memorialize the Extension.

Now, therefore, the Parties hereby agree as follows:

Amendments

1. Amendment to Section 2.1

Section 2.1 (Program Funding) of the Compact is amended and restated to read as follows:

''Section 2.1 *Program Funding.* Upon entry into force of this Compact in accordance with Section 7.3, MCC will grant to the Government, under the terms of this Compact, an amount not to exceed Three Hundred Seventy-Three Million, Five Hundred Nine Thousand, Eight Hundred Fourteen United States Dollars (US$373,509,814) (''*Program Funding*'') consisting of Two Hundred Seventy-Three Million, Five Hundred Nine Thousand, Eight Hundred Fourteen United States Dollars (US$273,509,814) (''*Tranche I Funding*''), Eighty Million United States Dollars (US$80,000,000) (''*On-Grid Tranche Funding*''), and Twenty Million United States Dollars (US$20,000,000) (''*Off-Grid Tranche Funding*''), for use by the Government to implement the Program. The allocation of Program Funding is generally described in *Annex II.*''

2. Amendment to Section 2.2

Section 2.2(a) (Compact Implementation Funding) of the Compact is amended and restated to read as follows:

''(a) Upon the signing of this Compact, MCC will grant to the Government, under the terms of this Compact and in addition to the Program Funding described in Section 2.1, an amount not to exceed Seventeen Million, Four Hundred Ninety Thousand, One

Hundred Eighty-Six United States Dollars (US$17,490,186) (''*Compact Implementation Funding*'') under Section 609(g) of the Millennium Challenge Act of 2003, as amended (the ''*MCA Act*''), for use by the Government to facilitate implementation of this Compact, including for the following purposes:

(i) Financial management and procurement activities;

(ii) administrative activities (including start-up costs such as staff salaries) and administrative support expenses such as rent, computers and other information technology or capital equipment;

(iii) monitoring and evaluation activities;

(iv) feasibility, design and other project preparatory studies; and

(v) other activities to facilitate Compact implementation as approved by MCC.

The allocation of Compact Implementation Funding is generally described in *Annex II.*''

3. Amendment to Section 7.4

Section 7.4 (Compact Term) of the Compact is amended and restated to read as follows:

''Section 7.4 *Compact Term.* This Compact will remain in force for six (6) years after its entry into force, unless terminated earlier under Section 5.1 (the ''*Compact Term*'').''

4. Amendments to Annex II (Multi-Year Financial Plan Summary)

(a) Section 2 of Annex II (Multi-Year Financial Plan Summary) to the Compact is amended and restated to read as follows:

''2. *Government Contribution.* During the Compact Term, the Government will make contributions, relative to its national budget and taking into account prevailing economic conditions, as are necessary to carry out the Government's responsibilities under Section 2.6(a) of this Compact. These contributions may include in-kind and financial contributions (including obligations of Benin on any debt incurred toward meeting these contribution obligations). In connection with this obligation the Government has developed a budget over the Compact Term to complement MCC Funding through budget allocations to each of the Projects and Program Administration. The Government will make a contribution of at least 7.5 percent of the amount of MCC Funding provided under this Compact over the Compact Term. The Government will allocate such contribution in the national budget according to a multi-year plan. The Government will provide evidence of the approval thereof to MCC prior to entry into force. In the event that deobligation of the On-Grid Tranche Funding or the Off-Grid Tranche Funding occurs in accordance with Section 8.3(a) of this Compact, the obligation for the corresponding Government contribution will cease to apply. Such contribution will be in addition to the Government's spending toward such Project Objectives in its budget for the year immediately preceding the establishment of this Compact. The Government's contribution will be subject to any legal requirements in Benin for the budgeting and appropriation of such contribution, including approval of the Government's budget by its legislature. The Parties may set forth in the Program Implementation Agreement or other appropriate Supplemental Agreements certain requirements regarding this Government contribution, which requirements may be conditions precedent to the Disbursement of MCC Funding. During implementation of the Program, the Government's contributions may be modified or new contributions added with MCC approval, provided that the modified or new contributions continue to advance the Project Objectives.''

(b) Exhibit A to Annex II (Multi-Year Financial Plan Summary) to the Compact is deleted in its entirety and replaced by revised Exhibit A set forth in *Annex I* to this Amendment.

General Provisions

1. Further Assurances

Each Party hereby covenants and agrees, without necessity of any further consideration, to execute and deliver any and all such further documents and take any and all such other action as may be reasonably necessary or appropriate to carry out the intent and purpose of this Amendment.

2. Effect of this Amendment

From and after the date this Amendment enters into force, the Compact and this Amendment will be read together and construed as one document, and each reference in the Compact to the ''Compact,'' ''hereunder,'' ''hereof'' or words of like import referring to the Compact, and each reference to the ''Compact,'' ''thereunder,'' ''thereof'' or words of like import in any Supplemental Agreement or in any other document or instrument delivered pursuant to the Compact or any Supplemental Agreement, will mean and be construed as a reference to the Compact, as amended by this Amendment.

3. Limitations

Except as expressly amended by this Amendment, all of the provisions of the Compact remain unchanged and in full force and effect.

4. Governing Law

The Parties acknowledge and agree that this Amendment is an international agreement entered into for the purpose of amending the Compact and as such will be interpreted in a manner consistent with the Compact and is governed by international law.

Annex I

REVISED EXHIBIT A TO ANNEX II TO THE COMPACT MULTI-YEAR FINANCIAL PLAN SUMMARY

	CIF	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
Compact Program Tranche I and CIF								
1. Policy Reform & Institutional Strengthening Project:								
1.1 Policy, Regulation, and Institutional Support Activity	3,501,904	729,664	2,578,737	760,008	4,051,526	360,072	54,000	12,035,911
1.2 Utility Strengthening Activity	1,105,247	9,204	65,153	14,123,285	699,852	.....	.....	16,002,741
1.3 Public Information & Education Activity	.....	.....	62,708	281,859	4,493	.....	.....	349,060
Sub-total	4,607,151	738,868	2,706,598	15,165,152	4,755,871	360,072	54,000	28,387,711
2. Electricity Generation Project—Tranche I:								
2.1 Photovoltaic Generation Activity (Tranche I)	3,046,236	.....	666,202	700,000	7,672,432	.....	.....	12,084,870
2.2 Thermal Generation Activity	583,270	.....	.....	.....	.....	.....	.....	583,270

REVISED EXHIBIT A TO ANNEX II TO THE COMPACT MULTI-YEAR FINANCIAL PLAN SUMMARY—Continued

	CIF	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
2.3 Hydroelectric Generation Activity	.....	.....	.....	.....	.....	.....	.....	.....
Sub-total	3,629,507	.....	666,202	700,000	7,672,432	.....	.....	12,668,141
3. Electricity Distribution Project:								
3.1 Regional Grid Strengthening Activity	.....	.....	.....	52,454,956	19,110	6,858,827	1,295,892	60,628,785
3.2 Cotonou Grid Strengthening Activity	.....	155,142	19,618,504	47,289,387	409,032	17,089,928	4,138,162	88,700,154
3.3 National Electricity Dispatch Activity	.....	8,533	22,668,572	1,550,680	.....	4,131,171	647,946	29,006,902
Sub-total	.....	163,675	42,287,076	101,295,023	428,142	28,079,926	6,082,000	178,335,841
4. Off-Grid Electricity Access Project—Tranche I:								
4.1 Off-Grid Clean Energy Facility Activity (Tranche I)	488,594	250,000	1,561,226	15,563,602	1,778,142	.....	2,500,000	22,141,563
4.2 Enabling Environment for Off-Grid Electricity Activity	1,347,439	.....	591,547	439,105	134,587	.....	.....	2,512,678
Sub-total	1,836,033	250,000	2,152,773	16,002,707	1,912,729	.....	2,500,000	24,654,241
5. Monitoring and Evaluation:								
5.1 Monitoring and Evaluation	107,674	.....	414,377	1,343,748	600,000	574,478	850,000	3,890,277
Sub-total	107,674	.....	414,377	1,343,748	600,000	574,478	850,000	3,890,277
6. Program Administration and Oversight:								
6.1 MCA-Benin II	5,608,216	1,534,203	2,839,077	4,365,037	4,516,182	5,970,679	4,514,000	29,347,393
6.2 Fiscal Agent	888,785	922,815	933,279	937,243	2,044,348	295,000	1,020,000	7,041,470
6.3 Procurement Agent	753,071	822,710	928,459	803,130	1,405,806	222,000	780,000	5,715,175
6.4 Audit	59,750	.....	121,500	578,500	.....	.....	200,000	959,750
Sub-total	7,309,822	3,279,728	4,822,315	6,683,910	7,966,335	6,487,679	6,514,000	43,063,789
Total MCC Funding—Tranche I &CIF	17,490,186	4,432,271	53,049,341	141,190,539	23,335,509	35,502,154	16,000,000	291,000,000
Compact Program On-Grid Tranche								
2. Electricity Generation Project—On-Grid Tranche:								
3.1 Regional Grid Strengthening Activity (On-Grid Tranche)	.....	.....	.....	20,000,000	.....	.....	.....	20,000,000
3.2 Cotonou Grid Strengthening Activity (On-Grid Tranche)	.....	.....	.....	60,000,000	.....	.....	.....	60,000,000
Total MCC Funding—On-Grid Tranche	.....	.....	.....	80,000,000	.....	.....	.....	80,000,000
Compact Program Tranche Off-Grid Tranche								
4. Off-Grid Electricity Access Project—Off-Grid Tranche:								
4.1 Off-Grid Clean Energy Facility Activity (Off-Grid Tranche)	.....	.....	.....	20,000,000	.....	.....	.....	20,000,000
Total MCC Funding—Off-Grid Tranche	.....	.....	.....	20,000,000	.....	.....	.....	20,000,000
Total MCC Funds	17,490,186	4,432,271	53,049,341	241,190,539	23,335,509	35,502,154	16,000,000	391,000,000

[FR Doc. 2021–17361 Filed 8–12–21; 8:45 am]

BILLING CODE 9211–03–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of August 16, 23, 30, September 6, 13, 20, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Week of August 16, 2021

There are no meetings scheduled for the week of August 16, 2021.

Week of August 23, 2021—Tentative

There are no meetings scheduled for the week of August 23, 2021.

Week of August 30, 2021—Tentative

There are no meetings scheduled for the week of August 30, 2021.

Week of September 6, 2021—Tentative

There are no meetings scheduled for the week of September 6, 2021.

Week of September 13, 2021—Tentative

Tuesday, September 14, 2021

10:00 a.m. Briefing on NRC International Activities (Closed—Ex. 1 & 9)

Week of September 20, 2021—Tentative

There are no meetings scheduled for the week of September 20, 2021.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov*. The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet

at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html*.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Betty.Thweatt@nrc.gov*.

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: August 11, 2021.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2021–17453 Filed 8–11–21; 11:15 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–122 and CP2021–124; MC2021–123 and CP2021–125; MC2021–124 and CP2021–126]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 17, 2021.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. Docket No(s).: MC2021–122 and CP2021–124; Filing Title: USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 9 to Competitive Product List and Notice of Filing Materials Under Seal; Filing Acceptance Date: August 9, 2021; Filing Authority: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; Public Representative: Kenneth R. Moeller; Comments Due: August 17, 2021.

2. Docket No(s).: MC2021–123 and CP2021–125; Filing Title: USPS Request to Add Priority Mail Contract 718 to Competitive Product List and Notice of Filing Materials Under Seal; Filing Acceptance Date: August 9, 2021; Filing Authority: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; Public Representative: Kenneth R. Moeller; Comments Due: August 17, 2021.

3. Docket No(s).: MC2021–124 and CP2021–126; Filing Title: USPS Request to Add Priority Mail Express Contract 90 to Competitive Product List and Notice of Filing Materials Under Seal; Filing Acceptance Date: August 9, 2021; Filing Authority: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; Public Representative: Christopher C. Mohr; Comments Due: August 17, 2021.

This Notice will be published in the **Federal Register**.

Jennie L. Jbara,

Alternate Certifying Officer.

[FR Doc. 2021–17355 Filed 8–12–21; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–121 and CP2021–123]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 16, 2021.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

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The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

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II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2021–121 and CP2021–123; *Filing Title:* USPS Request to Add Priority Mail Contract 717 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 6, 2021; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 16, 2021.

This Notice will be published in the **Federal Register**.

Jennie L. Jbara,

Alternate Certifying Officer.

[FR Doc. 2021–17296 Filed 8–12–21; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

RAILROAD RETIREMENT BOARD

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., August 25, 2021.

PLACE: Members of the public wishing to attend the meeting must submit a written request at least 24 hours prior to the meeting to receive dial-in information. All requests must be sent to *SecretarytotheBoard@rrb.gov*.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

(1) Payroll Tax Reimbursement from the IRS
(2) Pay For Time Lost (PFTL) Reporting Proposals:
  Proposal for BA–4 revision to identify PFTL
  Proposal for agency expansion of industry audits to include proper reporting of PFTL
(3) New proposals for improvements in communications to the public
(4) Update on status of appeals

CONTACT PERSON FOR MORE INFORMATION: Stephanie Hillyard, Secretary to the Board, (312) 751–4920.

Authority: 5 U.S.C. 552b.

Dated: August 11, 2021.

Stephanie Hillyard,

Secretary to the Board.

[FR Doc. 2021–17482 Filed 8–11–21; 11:15 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92615; File No. SR–NYSE–2021–41]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

August 9, 2021.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 2, 2021, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List to eliminate the (1) underutilized monthly rebate payable to Designated Market Makers (''DMM'') with 30 or fewer assigned securities, and (2) expired waivers for equipment and related service charges and trading license fees for NYSE Trading Floor-based member organizations. The Exchange proposes to implement the rule change on August 2, 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List to eliminate the (1) underutilized monthly rebate payable to DMMs with 30 or fewer assigned securities, and (2) expired waivers for equipment and related service charges and trading license fees for NYSE Trading Floor-based member organizations.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

The Exchange proposes to implement the rule change on August 2, 2021.

Proposed Rule Change

The Exchange proposes to eliminate an underutilized DMM rebate and obsolete waivers, as follows.

Underutilized DMM Rebate

The Exchange currently pays a DMM with 30 or fewer assigned securities a monthly rebate of $1,500 per security, up to a maximum of $10,000, for each security assigned to such a DMM in the previous month (regardless of whether the stock price exceeds $1.00) for which that DMM provides quotes at the National Best Bid (''NBB'') and National Best Offer (''NBO,'' together the ''NBBO'') at least 25% of the time in the applicable month. The monthly rebate is in addition to the current rate on transactions and is prorated to the number of trading days in a month that an eligible security is assigned to a DMM.

The Exchange proposes to eliminate this rebate in its entirety and to remove it from the Price List because the rebate has been underutilized by member organizations insofar as no DMMs with 30 or fewer assigned securities has qualified for the rebate in the past six months. As such, Exchange does not anticipate any member organization in the near future would qualify for the rebate that is the subject of this proposed rule change.

Expired Waivers

In response to the unprecedented events surrounding the spread of COVID–19 in 2020, the Exchange waived certain equipment and related service charges and trading license fees for NYSE Trading Floor-based member organizations beginning in June 2020 through the earlier of the first full month of a full reopening of the Trading Floor facilities to Floor personnel or June 2021.[4]

Specifically, the Exchange waived 50% of the Annual Telephone Line Charge of 400 per phone number; the $129 fee for a single line phone, jack, and data jack; the related service charges ($161.25 to install single jack (voice or data); $107.50 to relocate a jack; $53.75 to remove a jack; $107.50 to install voice or data line; $53.75 to disconnect data line; $53.75 to change a phone line subscriber; and miscellaneous telephone charges billed at $106 per hour in 15 minute increments); and the monthly portion of all applicable annual fees for member organizations that (1) had at least one trading license, a physical trading Floor presence and Floor broker executions accounting for 40% or more of the member organization's combined adding, taking and auction volumes during March 1 to March 20, 2020 or, if not a member organization during March 1 to March 20, 2020, based on the member organization's combined adding, taking, and auction volumes during its first month as a member organization on or after May 26, 2020, and (2) were unable to operate at more than 50% of their March 2020 on-Floor staffing levels or, for member organizations that began Floor operations after March 2020, are unable to operate at more than 50% of their Exchange-approved on-Floor staffing levels, both excluding part-time Floor brokers known as ''flex brokers''.

As set forth in footnotes 11 and 15 of the Price List, the waivers expired in June 2021 and have not been renewed. The Exchange accordingly proposes to delete footnote 11, which sets forth the equipment waivers described above, in its entirety, and to delete that portion of footnote 15 which addresses the waiver of the monthly portion of all applicable annual fees for member organizations, as obsolete.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[6] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed elimination of the monthly rebate of $1,500 per security, up to a maximum of $10,000, for DMMs with 30 or fewer assigned securities is reasonable because DMMs have underutilized the incentive. No DMM has qualified for the rebate in the past six months. The Exchange does not anticipate any member organization in the near future qualifying for the rebate that is the subject of this proposed rule change. The Exchange believes it is reasonable to eliminate requirements and credits when such incentives become underutilized. The Exchange also believes eliminating underutilized incentive programs would also simplify the Price List. The Exchange further believes that removing the optional DMM rebate and credit from the Price List would also add clarity and transparency to the Price List.

Further, the Exchange believes that it is reasonable to delete the expired waivers for NYSE Trading Floor-based member organizations from the Price List because the waivers are no longer offered and the fees are currently being charged. Deleting obsolete waivers would add greater clarity of the Exchange's rules and enable market participants to navigate the Exchange's Price List more easily.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes the proposal equitably allocates fees among its market participants because elimination of underutilized and ineffective DMM rebate and credits the Exchange proposes to eliminate would be eliminated in their entirety, and would no longer be available to any member organization in any form. Similarly, the Exchange believes the proposal equitably allocates fees among its market participants because elimination of obsolete waivers would apply to all similarly-situated member organizations on an equal basis. All such member organizations would continue to be subject to the same fee structure, and access to the Exchange's market would continue to be offered on fair and nondiscriminatory terms.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. The proposal is not unfairly discriminatory because it neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal is not unfairly discriminatory because the proposed elimination of the optional DMM rebate and credits would affect all similarly-

[4] *See* Securities Exchange Act Release No. 89050 (March 25, 2021), 86 FR 16798 (March 31, 2021) (SR–NYSE–2021–19). *See also* Securities Exchange Act Release No. 89050 (June 11, 2020), 85 FR 36637 (June 17, 2020) (SR–NYSE–2020–49); Securities Exchange Act Release No. 89324 (July 15, 2020), 85 FR 44129 (July 21, 2020) (SR–NYSE–2020–59); Securities Exchange Act Release No. 89754 (September 2, 2020), 85 FR 55550 (September 8, 2020) (SR–NYSE–2020–71); Securities Exchange Act Release No. 89798 (September 9, 2020), 85 FR 57263 (September 15, 2020) (SR–NYSE2020–72); Securities Exchange Act Release No. 90161 (October 13, 2020), 85 FR 66370 (October 19, 2020) (SR–NYSE–2020–81); Securities Exchange Act Release No. 90391 (November 10, 2020), 85 FR 73326 (November 17, 2020) (SR–NYSE2020–92); Securities Exchange Act Release No. 90744 (December 21, 2020), 85 FR 85712 (December 29, 2020) (SR–NYSE–2020–102); Securities Exchange Act Release No. 91082 (February 9, 2021), 86 FR 9546 (February 16, 2021) (SR–NYSE–2021–10).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) & (5).

situated market participants on an equal and non-discriminatory basis. The Exchange believes that eliminating optional DMM rebate and credits that are underutilized and ineffective would no longer be available to any DMM on an equal basis. Further, the proposal does not permit unfair discrimination because elimination of obsolete waivers would apply to all similarly situated member organizations on an equal basis. In addition, the Exchange believes that the proposed elimination of obsolete waivers would remove impediments to and perfect the mechanism of a free and open market by eliminating references to waivers that are no longer offered, thereby improving the clarity of the Exchange's rules and enabling market participants to more easily navigate the Exchange's Price List. The Exchange also believes that the proposed change would protect investors and the public interest because the deletion of underutilized and obsolete fees would make the Price List more accessible and transparent and facilitate market participants' understanding of the fees charged for services currently offered by the Exchange.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[7] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal relates solely to elimination of an underutilized rebate and obsolete waivers and, as such, would not have any impact on intra- or inter-market competition because the proposed change is solely designed to accurately reflect the services that the Exchange currently offers, thereby adding clarity to the Price List.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

[7] 15 U.S.C. 78f(b)(8).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[8] of the Act and subparagraph (f)(2) of Rule 19b–4[9] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[10] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2021–41 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2021–41. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2021–41 and should be submitted on or before September 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–17306 Filed 8–12–21; 8:45 am]

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[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(2).

[10] 15 U.S.C. 78s(b)(2)(B).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92617; File No. SR–FINRA–2021–008]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 1 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Change, as Modified by Amendment No. 1, Relating to Security-Based Swaps

August 9, 2021.

I. Introduction

On April 26, 2021, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–FINRA–2021–008 (''Proposed Rule Change'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act''),[1] and Rule 19b–4[2] thereunder, to amend FINRA Rules 0180, 4120, 4210, 4220, 4240 and 9610 to clarify the application of FINRA rules to security-based swaps (''SBS'') following the SEC's completion of its

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

rulemaking regarding SBS dealers (''SBSDs'') and major SBS participants (''MSBSPs'') (collectively, ''SBS Entities'').[3] The Proposed Rule Change was published for public comment in the **Federal Register** on May 12, 2021.[4] On June 14, 2021, FINRA consented to an extension of the time period in which the Commission must approve the Proposed Rule Change, disapprove the Proposed Rule Change, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change to August 10, 2021.[5] On August 9, 2021, FINRA responded to the comment letters received in response to the Notice and filed an amendment to modify the Proposed Rule Change (''Amendment No. 1'').[6] The Commission is publishing this order pursuant to Section 19(b)(2)(B) of the Exchange Act[7] to solicit comments on Amendment No. 1 from interested persons and to institute proceedings to determine whether to approve or disapprove the Proposed Rule Change, as modified by Amendment No. 1.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

FINRA is proposing to amend FINRA Rules 0180, 4120, 4210, 4220, 4240 and 9610 to take into account members' SBS activities once SBS Entities begin registering with the Commission on October 6, 2021. The proposed amendments to these rules generally fall into three categories. First, the Proposed Rule Change, as modified by Amendment No. 1, would adopt a new FINRA Rule 0180, to replace expiring current FINRA Rule 0180, that would generally apply FINRA rules to members' activities and positions with respect to SBS, while providing limited exceptions for those activities and positions in circumstances where FINRA believes such exceptions are appropriate. Second, the Proposed Rule Change, as modified by Amendment No. 1, would amend FINRA's financial responsibility and operational rules for SBSDs and broker-dealers to conform to the SEC's amendments to its capital, margin and segregation requirements,[8] and to otherwise take into account members' SBS activities. Third, the Proposed Rule Change, as modified by Amendment No. 1, would adopt a new margin rule specifically applicable to SBS, which would replace the expiring interim pilot program establishing margin requirements for credit default swaps.

Amendment No. 1 would make the following changes to the Proposed Rule Change: (1) Extend the effective date of the proposed amendments to FINRA Rules 0180, 4120 and 9610 from October 6, 2021 to February 6, 2022; (2) extend the effective date of the proposed amendments to FINRA Rules 4210, 4220 and 4240 from October 6, 2021 to April 6, 2022; and (3) conform the proposed definition of Legacy Swap in proposed FINRA Rule 4240(d)(12) to reflect the new effective date of April 6, 2022.

III. Proceedings To Determine Whether To Approve or Disapprove File No. SR–FINRA–2021–008 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act to determine whether the Proposed Rule Change, as modified by Amendment No. 1, should be approved or disapproved.[9] Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the Proposed Rule Change, as modified by Amendment No. 1. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to the Proposed Rule Change, as modified by Amendment No. 1.

Pursuant to Section 19(b)(2)(B) of the Exchange Act,[10] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis and input concerning whether the Proposed Rule Change, as modified by Amendment No. 1, is consistent with the Exchange Act and the rules thereunder.

IV. Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the Proposed Rule Change, as modified by Amendment No. 1. In particular, the Commission invites the written views of interested persons concerning whether the Proposed Rule Change, as modified by Amendment No. 1, is consistent with the Exchange Act and the rules thereunder.

Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[11]

Interested persons are invited to submit written data, views, and arguments regarding whether the Proposed Rule Change, as modified by Amendment No. 1, should be approved or disapproved by August 30, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by September 3, 2021.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–FINRA–2021–008 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–FINRA–2021–008. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the Proposed Rule Change, as modified by Amendment No. 1, that are filed with the Commission, and all written communications relating

[3] Exchange Act Release No. 91789, (May 7, 2021), 86 FR 26084 (May 12, 2021) (File No. SR–FINRA–2021–008) (''Notice'').

[4] *See id.*

[5] *See* letter from Robert McNamee, Assistant General Counsel, Office of General Counsel, FINRA, to Daniel Fisher, Division of Trading and Markets, Commission, dated June 14, 2021.

[6] *See* letter from Robert McNamee, Assistant General Counsel, Office of General Counsel, FINRA to Vanessa Countryman, Secretary, Commission, dated August 9, 2021.

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital and Segregation Requirements for Broker-Dealers, Exchange Act Release No. 86175, (Jun. 21, 2019), 84 FR 43872 (Aug. 22, 2019) (File No. S7–08–12).

[9] 15 U.S.C. 78s(b)(2)(B).

[10] *Id.*

[11] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29, 89 Stat. 97 (1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Report of the Senate Committee on Banking, Housing and Urban Affairs to Accompany S. 249, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

to the Proposed Rule Change, as modified by Amendment No. 1, between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File No. SR–FINRA–2021–008 and should be submitted on or before August 30, 2021. If comments are received, any rebuttal comments should be submitted on or before September 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–17307 Filed 8–12–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92610; File No. SR–NYSEArca–2021–31]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the Valkyrie Bitcoin Fund Under NYSE Arca Rule 8.201–E

August 9, 2021.

On April 23, 2021, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the Valkyrie Bitcoin Fund (''Trust'') under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares). The proposed rule change was published for comment in the **Federal Register** on May 12, 2021.[3]

On June 22, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] This order institutes proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.

I. Summary of the Proposal

As described in more detail in the Notice,[7] the Exchange proposes to list and trade the Shares of the Trust under NYSE Arca Rule 8.201–E, which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

The investment objective of the Trust will be for the Shares to reflect the performance of the value of a bitcoin as represented by the CF Bitcoin US Settlement Price (''Index''), less the Trust's liabilities and expenses.[8] The Fund will use the Index to calculate the Trust's net asset value (''NAV'').[9] The Index serves as a once-a-day benchmark rate of the U.S. dollar price of bitcoin (USD/BTC), calculated as of 4:00 p.m., E.T. The Index aggregates the trade flow of several bitcoin exchanges, during an observation window between 3:00 p.m. and 4:00 p.m., E.T., into the U.S. dollar price of one bitcoin at 4:00 p.m., E.T. The current constituent bitcoin exchanges of the Index are Bitstamp, Coinbase, Gemini, itBit, and Kraken (''Constituent Bitcoin Exchanges''). In calculating the Index, the methodology creates a joint list of certain trade prices and sizes from the Constituent Bitcoin Exchanges between 3:00 p.m. and 4:00 p.m., E.T. The methodology then divides this list into 12 equally-sized time intervals of 5 minutes and it calculates the volume-weighted median trade price for each of those time intervals. The Index is the arithmetic mean of these 12 volume-weighted median trade prices.[10]

The Shares of the Trust represent units of fractional undivided beneficial interest in, and ownership of, the Trust. The Trust will only hold bitcoin. The Custodian will establish accounts that hold the bitcoins deposited with the Custodian on behalf of the Trust.[11]

The Administrator will calculate the NAV of the Trust once each Exchange trading day. The Sponsor will publish the NAV and NAV per Share as soon as practicable after their determination and availability, and the NAV will be released after the end of the Core Trading Session (4:00 p.m., E.T.). The NAV of the Trust is not officially struck until later in the day (often by 5:30 p.m., E.T, and usually by 8:00 p.m., E.T.). The Trust's NAV per Share is calculated by taking the current market value of its total assets, less any liabilities of the Trust, and dividing that total by the total number of outstanding Shares. The bitcoin held by the Trust will be valued based on the price set by the Index.[12]

The Trust will provide website disclosure of its bitcoin holdings daily.[13] The Trust will also disseminate an intraday indicative value (''IIV'') per Share updated every 15 seconds by one of more major market data vendors during the Exchange's Core Trading Session (normally 9:30 a.m. to 4:00 p.m., E.T.). The IIV will be calculated by a third-party financial data provider using the prior day's closing NAV per Share of the Trust as a base and updating that value throughout the trading day to reflect changes in the most recently reported price level of the CME CF Bitcoin Real-Time Index (''BRTI''), as reported by CME Group, Inc., Bloomberg, L.P., or another reporting service.[14]

The Trust will issue and redeem Shares to authorized participants on an ongoing basis in one or more ''Baskets'' of 50,000 Shares. The creation and redemption of a Basket requires the delivery to the Trust, or the distribution by the Trust, of the number of whole and fractional bitcoins represented by

[12] 17 CFR 200.30–3(a)(12); 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91771 (May 6, 2021), 86 FR 26073 (May 12, 2021) (''Notice''). Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-nysearca-2021-31/srnysearca202131.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92233 (June 22, 2021), 86 FR 34107 (June 28, 2021). The Commission designated August 10, 2021, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Notice, *supra* note 3.

[8] Valkyrie Digital Assets LLC is the sponsor of the Trust (''Sponsor'') and Delaware Trust Company is the trustee. Coinbase Custody Trust Company, LLC (''Custodian'') will act as custodian for the Trust's bitcoins. U.S. Bancorp Fund Services, LLC (''Administrator'') will act as the transfer agent and administrator of the Trust. *See* Notice, *supra* note 3, 86 FR at 26073.

[9] The Index is not affiliated with the Sponsor and is administered by CF Benchmarks Ltd. (''Benchmark Administrator''). *See* Notice, *supra* note 3, 86 FR at 26076.

[10] *See id.*

[11] *See id.* at 26073.

[12] *See id.* at 26076.

[13] *See id.* at 26081.

[14] The BRTI is calculated in real time based on the universe of the currently unmatched limit orders to buy or sell in the BTC/USD pair of all Constituent Bitcoin Exchanges. *See id.* at 26076.

each Basket being created or redeemed.[15] Creation orders and redemption orders may be placed either ''in-kind'' or ''in-cash.'' Although the Trust will create Baskets only upon the receipt of bitcoins, and will redeem Baskets only by distributing bitcoins, an authorized participant may deposit cash with the Administrator, which will facilitate the purchase or sale of bitcoins through a liquidity provider on behalf of an authorized participant (''Conversion Procedures'').[16]

II. Proceedings To Determine Whether To Approve or Disapprove SR–NYSEArca–2021–31 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[17] to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change, as discussed below. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[18] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices'' and ''to protect investors and the public interest.'' [19]

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice,[20] in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following questions and asks commenters to submit data where appropriate to support their views:

1. What are commenters' views on whether the proposed Trust and Shares would be susceptible to manipulation? What are commenters' views generally on whether the Exchange's proposal is designed to prevent fraudulent and manipulative acts and practices? What are commenters' views generally with respect to the liquidity and transparency of the bitcoin markets, the bitcoin markets' susceptibility to manipulation, and thus the suitability of bitcoin as an underlying asset for an exchange-traded product?

2. What are commenters' views of the Exchange's assertion that the bitcoin ecosystem has matured considerably since the last time the Commission reviewed a proposal for a bitcoin exchange-traded product? [21] Are the changes that the Exchange identifies sufficient to support the determination that the proposed listing and trading of the Shares is consistent with the Act?

3. The Exchange states that the design choices within the methodology and framework of the Index are sufficiently resistant to market manipulation and that, to date, there has been no evidence that the Index has been subject to manipulation.[22] What are commenters' views on these assertions regarding the Index, including the relevance of such assertions in determining whether the proposed listing and trading of the Shares is consistent with the Act?

4. The Exchange states that the Chicago Mercantile Exchange (''CME'') participates in the oversight committee of the Index.[23] The Exchange further states that the Constituent Bitcoin Exchanges ''(1) must enter into a data sharing agreement with the CME, (2) must cooperate with inquiries and investigations of regulators and the Benchmark Administrator and (3) must submit each of its clients to its Know-Your-Customer (''KYC'') procedures; therefore, the CME would be able, in the case of any suspicious trades, to discover all material trade information including the identities of the customers placing the trades.'' [24] What are commenters' views on these assertions regarding the Index, including the relevance of such assertions in determining whether the proposed listing and trading of the Shares is consistent with the Act?

5. The Exchange states that the ''proposed rule change is designed to prevent fraudulent and manipulative acts and practices because, although the global Bitcoin market is not inherently resistant to fraud and manipulation, the Index used by the Trust to determine the value of its bitcoin assets and its NAV, serves as a benchmark mechanism sufficient to mitigate the impact of instances of fraud and manipulation on a reference price for Bitcoin.'' [25] The Exchange further states that ''use of the Index would mitigate the effects of potential manipulation of the bitcoin market.'' [26] What are commenters' views regarding such assertions?

III. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[27]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by September 3, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by September 17, 2021.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2021–31 on the subject line.

[15] *See id.* at 26076–77.

[16] The Conversion Procedures will be facilitated by a single liquidity provider, which will be selected by the Sponsor on an order-by-order basis. In the event that an order cannot be filled in its entirety by a single liquidity provider, additional liquidity provider(s) will be selected by the Sponsor to fill the remaining amount. *See id.* at 26076–78.

[17] 15 U.S.C. 78s(b)(2)(B).

[18] *Id.*

[19] 15 U.S.C. 78f(b)(5).

[20] *See* Notice, *supra* note 3.

[21] *See id.* at 26078.

[22] *See id.* at 26078–79.

[23] *See id.* at 26079.

[24] *See id.*

[25] *See id.* at 26080.

[26] *See id.*

[27] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2021–31. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2021–31 and should be submitted by September 3, 2021. Rebuttal comments should be submitted by September 17, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–17305 Filed 8–12–21; 8:45 am]

BILLING CODE 8011–01–P

[28] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92614; No. SR–NYSEArca–2021–69]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

August 9, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 4, 2021, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule (''Fee Schedule''). The Exchange proposes to implement the fee change effective August 4, 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Fee Schedule to remove language associated with a fee waiver and a credit that expired at the close of business on June 30, 2021.

On March 18, 2020, the Exchange announced that it would temporarily close the Trading Floor, effective March 23, 2020, as a precautionary measure to prevent the potential spread of COVID–19. Following the temporary closure of the Trading Floor, the Exchange waived certain Floor-based fixed fees for April and May 2020.[4] Although the Trading Floor partially reopened on May 4, 2020 and Floor-based open outcry activity was supported, certain participants were unable to resume pre-Floor closure levels of operations. As a result, the Exchange extended the fee waiver through June 2021, but only for Floor Broker firms that were unable to operate at more than 50% of their March 2020 on-Floor staffing levels and for Market Maker firms that had vacant or ''unmanned'' Podia for the entire month due to COVID–19 related considerations (the ''Qualifying Firms'').[5]

Because the Trading Floor continued to operate with reduced capacity, the Exchange extended the fee waiver for Qualifying Firms through ''the earlier of the first full month of a full reopening of the Trading Floor facilities to Floor personnel or June 2021''. The Trading Floor re-opened without social distancing requirements for vaccinated personnel on May 12, 2021.

Additionally, in May 2021, the Exchange implemented an incentive to encourage Floor Brokers to increase their Professional Customer billable volume.[6] Specifically, the Exchange offered Floor Brokers a credit of $0.13 per contract for each billable

[4] *See* Securities Exchange Act Release Nos. 88596 (April 8, 2020), 85 FR 20796 (April 14, 2020) (SR–NYSEArca–2020–29); 88812 (May 5, 2020), 85 FR 27787 (May 11, 2020) (SR–NYSEArca–2020–38).

[5] *See* Securities Exchange Act Release Nos. 89038 (June 10, 2020), 85 FR 36447 (June 16, 2020) (SR–NYSEArca–2020–52); 89242 (June 7, 2020), 85 FR 42037 (July 13, 2020) (SR–NYSEArca–2020–60); 89480 (August 5, 2020), 85 FR 48591 (August 11, 2020) (SR–NYSEArca–2020–69); 89694 (August 27, 2020), 85 FR 54608 (September 2, 2020) (SRNYSEArca–2020–76); 90191 (October 15, 2020), 85 FR 67032 (October 21, 2020) (SRNYSEArca–2020–90); 90838 (December 31, 2020), 86 FR 657 (January 6, 2021) (SRNYSEArca–2020–115), 91372 (March 18, 2021) 86 FR 15980 (March 25, 2021) (SR–NYSEArca–2021–18).

[6] *See* Exchange Act Release No. 91936 (May 19, 2021) 86 FR 28178 (May 25, 2021) (SR–NYSEArca–2021–41).

Professional Customer contract that exceeded a baseline average daily volume for the month. This fee incentive was adopted with a stated expiration at the close of business on June 30, 2021.

As the expiration date for both the fee waiver and the fee incentive has passed, the Exchange is submitting this proposed rule change to remove language related to the fee waiver and the fee incentive from the Fee Schedule.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[8] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed modifications to the Fee Schedule to remove an expired fee waiver and an expired fee incentive that the Exchange no longer offers are reasonable, equitable, and not unfairly discriminatory because the changes would provide clarity to the Fee Schedule, and do not affect any current activity by any OTP Holder or OTP Firm.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the proposed change is meant to add clarity and transparency to the Fee Schedule to the benefit of all market participants that trade on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[9] of the Act and subparagraph (f)(2) of Rule 19b–4[10] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[11] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2021–69 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2021–69. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2021–69, and should be submitted on or before September 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–17304 Filed 8–12–21; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4) and (5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(2).

[11] 15 U.S.C. 78s(b)(2)(B).

[12] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 11492]

60-Day Notice of Proposed Information Collection: DS–160, Online Application for Nonimmigrant Visa and DS–156, Nonimmigrant Visa Application

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collections described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *October 12, 2021.*

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2021–0023'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.

FOR FURTHER INFORMATION CONTACT: D. Aikens at *PRA_BurdenComments@state.gov* or over telephone at (202)–485–7586.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Electronic Application for Immigrant Visa and Alien Registration
- *OMB Control Number:* 1405–0182
- *Type of Request:* Revision of a Currently Approved Collection
- *Originating Office:* CA/VO
- *Form Number:* DS–160, DS–156
- *Respondents:* Immigrant Visa Applicants
- *Estimated Number of Respondents:* 5,190,367
- *Estimated Number of Responses:* 5,190,367
- *Average Time per Response:* 90 minutes
- *Total Estimated Burden Time:* 7,785,550.5 hours
- *Frequency:* Once per respondent's application
- *Obligation to respond:* Required to Obtain or Retain a Benefit

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden of this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The DS–160 and DS–156 collect biographical information from individuals seeking a nonimmigrant visa. The consular officer uses the information collected to elicit information necessary to determine an applicant's eligibility for a visa. Most nonimmigrant visa applicants, as well as certain authorized parole applicants use the DS–160, however posts may authorize an applicant to use the paper-based DS–156 in limited circumstances as outlined below.

Methodology

The applicant submits the DS–160 electronically over an encrypted connection to the Department via the internet. The applicant will be instructed to print a confirmation page containing a bar coded record locator, which the consular office will use to locate the application during processing.

The DS–156 is a paper-based version of the DS–160. In order to obtain a copy of the DS–156, an applicant must contact the Embassy or consulate at which he or she is applying and request a copy. A consular officer may allow an applicant to submit the DS–156 in the following limited circumstances when applicants cannot access the DS–160:

- An applicant has an urgent medical or humanitarian travel need and the consular officer has received explicit permission from the Visa Office to accept form DS–156;
- The applicant is a student exchange visitor who must leave immediately in order to arrive on time for his/her course and the consular officer has explicit permission from the Visa Office to accept form DS–156;
- The applicant is a diplomatic or official traveler with urgent government business and form DS–160 has been unavailable for more than four hours; or
- Form DS–160 has been unavailable for more than three days and the officer receives explicit permission from the Visa Office.

The DS–160 is also used in limited circumstances to process certain parole applicants. When a humanitarian or significant public benefit parole request is authorized by USCIS, the applicants are required to complete the DS–160 and appear for an appointment with the Department of State consular section to verify their identity and collect biometrics for additional security vetting. If no new derogatory information or new identity information is identified during vetting that would cause USCIS to rescind parole approval, the U. S. Consulate issues a document referred to as a boarding foil that allows the beneficiary to travel to the United States within 30 days of it being issued. A final determination on whether to parole an applicant into the United States is then made by CBP at the port of entry.

Kevin E. Bryant,

Deputy Director, Office of Directives Management, Department of State.

[FR Doc. 2021–17332 Filed 8–12–21; 8:45 am]

BILLING CODE 4710–06–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36527]

South Kansas and Oklahoma Railroad, L.L.C.—Lease and Operation Exemption—Tulsa's Port of Catoosa Facilities Authority

South Kansas and Oklahoma Railroad, L.L.C. (SKOR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease from Tulsa's Port of Catoosa Facilities Authority (the Port) and continue to operate a line of railroad extending approximately 7.1 miles between milepost 0.00, in Owasso, Okla., and milepost 7.07, in Catoosa, Okla. (the Line).

The verified notice states that SKOR previously operated the Line pursuant to assignment of a leasehold from the former Atchison, Topeka & Santa Fe Railway Company. *See S. Kan. & Okla. R.R.—Lease Exemption—The Atchison, Topeka & Santa Fe Ry.,* FD 32082 (ICC served Aug. 11, 1992).[1] SKOR and the Port have entered into a new Rail Line Lease Agreement (the Lease Agreement) to govern the subject transaction. SKOR intends to continue common carrier operations on the Line under the terms of the Lease Agreement.

According to SKOR, the Lease Agreement does not include an interchange commitment. Further, SKOR certifies that its projected annual revenues as a result of this transaction will not result in SKOR's becoming a Class II or Class I rail carrier, but that its current annual revenues exceed $5 million. Pursuant to 49 C.F.R 1150.42(e), if a carrier's projected annual revenues will exceed $5 million, it must, at least 60 days before this exemption is to become effective, post a notice of its intent to undertake the proposed transaction at the workplace of the employees on the affected lines, serve a copy of the notice on the national offices of the labor unions with employees on the affected lines, and certify to the Board that it has done so. However, SKOR has filed a petition for waiver of the 60-day advance labor notice requirements. SKOR's waiver request will be addressed in a separate decision. The Board will establish the effective date of the exemption in its separate decision on the waiver request.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of

[1] SKOR states that the 7.1 miles identified in this notice is a more accurate measurement of the Line than the 7.3 miles given in Docket No. FD 32082.

a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than August 20, 2021.

All pleadings, referring to Docket No. FD 36527, should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, one copy of each pleading must be served on SKOR's representative, Bradon J. Smith, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

According to SKOR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: August 10, 2021.

By the Board, Valerie O. Quinn, Acting Director, Office of Proceedings.

Eden Besera,

Clearance Clerk.

[FR Doc. 2021–17387 Filed 8–12–21; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Joint notice, request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the OCC, the Board, and the FDIC (the agencies) may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The Federal Financial Institutions Examination Council (FFIEC), of which the agencies are members, has approved the agencies' publication for public comment of a proposal to extend for three years, without revision, the Foreign Branch Report of Condition (FFIEC 030) and the Abbreviated Foreign Branch Report of Condition (FFIEC 030S).

DATES: Comments must be submitted on or before October 12, 2021.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the ''FFIEC 030 or FFIEC 030S,'' will be shared among the agencies.

OCC: You may submit comments, which should refer to ''FFIEC 030 or FFIEC 030S,'' by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Office of the Comptroller of the Currency, Attention: 1557–0099, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

Instructions: You must include ''OCC'' as the agency name and ''1557–0099'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the following method:

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' link on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0099.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

Board: You may submit comments, which should refer to ''FFIEC 030 or FFIEC 030S,'' by any of the following methods:

- Agency Website: *http://www.federalreserve.gov.* Follow the instructions for submitting comments at: *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Email: regs.comments@federalreserve.gov.* Include ''FFIEC 030 or FFIEC 030S'' in the subject line of the message.
- *Fax:* (202) 395–6974.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available on the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information.

FDIC: You may submit comments, which should refer to ''FFIEC 030 or FFIEC 030S,'' by any of the following methods:

- *Agency Website: https://www.fdic.gov/regulations/laws/federal/.* Follow the instructions for submitting comments on the FDIC's website.
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: comments@FDIC.gov.* Include ''FFIEC 030 or FFIEC 030S'' in the subject line of the message.
- *Mail:* Manuel E. Cabeza, Counsel, Attn: Comments, Room MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.
- *Public Inspection:* All comments received will be posted without change to *https://www.fdic.gov/regulations/laws/federal/* including any personal information provided. Paper copies of public comments may be requested from the FDIC Public Information Center by telephone at (877) 275–3342 or (703) 562–2200.

Additionally, commenters may send a copy of their comments to the OMB desk officer for the agencies by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503; by fax to (202)

395–6974; or by email to *oira_submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: For further information about the proposed revisions to the information collections discussed in this notice, please contact any of the agency staff whose names appear below. In addition, copies of the report forms for the FFIEC 030 and FFIEC 030S can be obtained at the FFIEC's website (*https://www.ffiec.gov/ffiec_report_forms.htm*).

OCC: Kevin Korzeniewski, Counsel, Chief Counsel's Office, (202) 649–5490.

Board: Nuha Elmaghrabi, Federal Reserve Board Clearance Officer, (202) 452–3884, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869.

FDIC: Manuel E. Cabeza, Counsel, (202) 898–3767, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: The agencies propose to extend for three years, without revision, the FFIEC 030 and the FFIEC 030S.

Report Title: Foreign Branch Report of Condition.

Form Number: FFIEC 030 and FFIEC 030S.

Frequency of Response: Annually, and quarterly for significant branches.

Affected Public: Business of other for profit.

OCC

OMB Control Number: 1557–099.

Estimated Number of Respondents: 56 quarterly respondents (FFIEC 030); 46 annual respondents (FFIEC 030); 15 annual respondents (FFIEC 030S).

Estimated Average Burden per Response: 3.4 burden hours (FFIEC 030); 0.5 burden hours (FFIEC 030S).

Estimated Total Annual Burden: 926 burden hours.

Board

OMB Control Number: 7100–0071.

Estimated Number of Respondents: 20 quarterly respondents (FFIEC 030); 12 annual respondents (FFIEC 030); 7 annual respondents (FFIEC 030S).

Estimated Average Burden per Response: 3.4 burden hours (FFIEC 030); 0.5 burden hours (FFIEC 030S).

Estimated Total Annual Burden: 316 burden hours.

FDIC

OMB Control Number: 3064–0011 (FDIC).

Estimated Number of Respondents: 1 quarterly respondent (FFIEC 030); 3 annual respondents (FFIEC 030); 3 annual respondents (FFIEC 030S).

Estimated Average Burden per Response: 3.4 burden hours (FFIEC 030); 0.5 burden hours (FFIEC 030S).

Estimated Total Annual Burden: 25 burden hours.

I. Legal Basis and Need for Collection

This information collection is mandatory under the following authorities: 12 U.S.C. 602 (Board); 12 U.S.C. 161 and 602 (OCC); and 12 U.S.C. 1828 (FDIC). This information collection is given confidential treatment under 5 U.S.C. 552(b)(4) and (8).

The FFIEC 030 collects asset and liability information for foreign branches of insured U.S. banks and insured U.S. savings associations (U.S. depository institutions) and is required for regulatory and supervisory purposes. The information is used to analyze the foreign operations of U.S. institutions. All foreign branches of U.S. institutions regardless of charter type file this report as provided in the instructions to the FFIEC 030 and FFIEC 030S.

A U.S. depository institution generally must file a separate report for each foreign branch, but in some cases may consolidate filings for multiple foreign branches in the same country, as described below.

A branch with either total assets of at least $2 billion or commitments to purchase foreign currencies and U.S. dollar exchange of at least $5 billion as of the end of a calendar quarter is considered a ''significant branch'' and an FFIEC 030 report is required to be filed quarterly. A U.S. depository institution with a foreign branch having total assets in excess of $250 million that does not meet either of the criteria to file quarterly must file the entire FFIEC 030 report for this foreign branch on an annual basis as of December 31.

A U.S. depository institution with a foreign branch having total assets of $50 million, but less than or equal to $250 million that does not meet the criteria to file the FFIEC 030 report must file the FFIEC 030S report for this foreign branch on an annual basis as of December 31. A U.S. depository institution with a foreign branch having total assets of less than $50 million is exempt from filing the FFIEC 030 and 030S reports.

II. Request for Comment

Public comment is requested on all aspects of this notice. Comment is specifically invited on:

a. Whether the information collection is necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

b. The accuracy of the agencies' estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted to the Board in response to this notice will be shared with the other agencies. All comments will become a matter of public record.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on August 6, 2021.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021–17311 Filed 8–12–21; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Meaningful Access Information Collections

AGENCY: Bureau of Engraving and Printing, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Bureau of Engraving and Printing (BEP), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to comment on the proposed information collections listed below, in accordance with the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before October 12, 2021.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to Tracy Garret, Bureau of Engraving and Printing, 14th and C Streets SW, Washington, DC 20228.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Tracy Garrett by emailing *Tracy.Garrett@bep.gov,* calling (202) 874–3256, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for Meaningful Access Information Collections.

OMB Control Number: 1520–0009.

Type of Review: Extension of a currently approved collection.

Description: A court order was issued in *American Council of the Blind* v. *Paulson,* 591 F. Supp. 2d 1 (D.D.C. 2008) (''*ACB* v. *Paulson*'') requiring the Department of the Treasury and BEP to ''provide meaningful access to United States currency for blind and other visually impaired persons, which steps shall be completed, in connection with each denomination of currency, not later than the date when a redesign of that denomination is next approved by the Secretary of the Treasury. . . .''

In compliance with the court's order, BEP intends to meet with blind and visually impaired persons and request their feedback about tactile features that BEP is considering for possible incorporation into the next U.S. paper currency redesign. BEP employees will attend national conventions and conferences for disabled persons, as well as focus groups and other meetings. At those gatherings, BEP employees will invite blind and visually impaired persons to provide feedback about certain tactile features being considered for inclusion in future United States currency paper designs. In the past BEP contracted with specialists in the field of tactile acuity to develop a methodology for collecting the feedback. This same or substantially similar methodology will be used to continue this information collection.

Over the next three years, the BEP anticipates undertaking a variety of new information collection activities related to BEP's continued efforts to provide meaningful access to U.S. paper currency for blind and visually impaired persons. Following standard OMB requirements, for each information collection that BEP proposes to undertake under this generic clearance, the OMB will be notified at least two weeks in advance and provided with a copy of the information collection instrument along with supportive materials. The BEP will only undertake a new collection if the OMB does not object to the BEP's proposal.

Form: None.

Affected Public: Individuals and households, Businesses and other for-profits, Not-for-profit Institutions.

Estimated Number of Respondents: 650.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 650.

Estimated Time per Response: 60 minutes.

Estimated Total Annual Burden Hours: 650 hours.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: August 10, 2021.

Katherine A. Allen,

BEP PRA Clearance Officer.

[FR Doc. 2021–17334 Filed 8–12–21; 8:45 am]

BILLING CODE 4840–01–P

DEPARTMENT OF VETERANS AFFAIRS

Health Services Research and Development Service Scientific Merit Review Board, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App.2, that a meeting of the Health Services Research and Development Service Scientific Merit Review Board will be held September 2, 2021, via WebEx. The meeting will be held between noon and 1:00 p.m. EST. The meeting will be partially closed to the public from 12:15–1:00 p.m. EST for the discussion, examination and reference to the research applications and scientific review. Discussions will involve reference to staff and consultant critiques of research proposals. Discussions will deal with scientific merit of each proposal and qualifications of personnel conducting the studies, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Additionally, premature disclosure of research information could significantly obstruct implementation of proposed agency action regarding the research proposals. As provided by Public Law 92–463 subsection 10(d), as amended by Public Law 94–409, closing the committee meeting is in accordance with 5 U.S.C. 552b(c) (6) and (9)(B).

The objective of the Board is to provide for the fair and equitable selection of the most meritorious research projects for support by VA research funds and to offer advice for research program officials on program priorities and policies. The ultimate objective of the Board is to ensure the high quality and mission relevance of VA's legislatively mandated Health Services Research and Development program.

Board members advise the Director, Health Services Research and Development Service and the Chief Research and Development Officer on the scientific and technical merit, the mission relevance and the protection of human subjects of Health Services Research and Development proposals. The Board does not consider grants, contracts or other forms of extramural research.

Members of the public who wish to attend the open portion of the teleconference session from 12:00–12:15 p.m. EST may join by dialing the Webex USA Toll-free Number 1–833–558–0712 and entering the meeting number (access code): 199 514 5335.

Written comments from the public must be sent to Liza Catucci, Designated Federal Officer, Health Services Research and Development Service, Department of Veterans Affairs (14RDH), 810 Vermont Avenue NW, Washington, DC 20420, or to *Liza.Catucci@va.gov* prior to the meeting. Those who plan to attend the open portion of the meeting must contact Ms. Catucci at least five days before the meeting. For further information, please call Ms. Catucci at 202–443–5797.

Dated: August 10, 2021.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–17385 Filed 8–12–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–XXXX]

Agency Information Collection Activity Under OMB Review: Receipt of Supplies (Chapter 31—Veteran Readiness and Employment)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–XXXX.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–XXXX'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 United States Code (U.S.C.) 3104(a)(7).

Title: Receipt of Supplies (Chapter 31—Veteran Readiness and Employment), VA Form 28–1905r.

OMB Control Number: 2900–XXXX.

Type of Review: Request for approval of a new collection.

Abstract: A claimant will use VA Form 28–1905r, Receipt of Supplies (Chapter 31—Veteran Readiness and Employment), to verify that the supplies and/or equipment provided as part of a rehabilitation program under 38 U.S.C. Chapter 31 have been received and are in good condition. The VR&E program subsequently uses the information on this form to justify processing payments for the supplies and/or equipment provided to claimants under 38 U.S.C. 3104(a)(7). Without the information gathered on this form, the VR&E program would be unable to verify that the claimant received the supplies and/or equipment, which could result in inaccurate payments being rendered.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 13, 2021 on page 26,257.

Affected Public: Individuals or Households.

Estimated Annual Burden: 4,667 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 28,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–17295 Filed 8–12–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0501]

Agency Information Collection Activity: Agency Information Collection Activity: Veterans Mortgage Life Insurance Inquiry

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administrations, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed from Veterans for the proper maintenance of Veterans Mortgage Life Insurance accounts.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before October 12, 2021.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0501'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0501'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Veterans Mortgage Life Insurance Inquiry (VA Form 29–0543).

OMB Control Number: 2900–0501.

Type of Review: Extension of a previously approved collection.

Abstract: The Veterans Mortgage Life Insurance Inquiry solicits information needed from Veterans for the proper maintenance of Veterans Mortgage Life Insurance accounts. The form is authorized by 38 U.S.C. 2106 and 38 CFR 8a.3(e).

Affected Public: Individuals and households.

Estimated Annual Burden: 17 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 200.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–17324 Filed 8–12–21; 8:45 am]

BILLING CODE 8320–01–P

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 425, et al.

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 425, 455, and 495

[CMS–1752–F and CMS–1762–F]

RINs 0938–AU44 and 0938–AU56

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2022 and to implement certain recent legislation. The final rule also updates the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2022. It also finalizes a May 10, 2021 interim final rule with comment period regarding rural reclassification through the Medicare Geographic Classification Review Board (MGCRB). The final rule also implements changes and updates for the Medicare Promoting Interoperability, Hospital Value-Based Purchasing, Hospital Readmissions Reduction, Hospital Inpatient Quality Reporting, Hospital-Acquired Condition Reduction, the PPS-Exempt Cancer Hospital Reporting, and the Long-Term Care Hospital Quality Reporting programs. It also finalizes provisions that alleviate a longstanding problem related to claiming Medicare bad debt and provide a participation opportunity for eligible accountable care organizations (ACOs).

DATES: This final rule is effective October 1, 2021.

FOR FURTHER INFORMATION CONTACT:

Donald Thompson, (410) 786–4487, and Michele Hudson, (410) 786–4487, Operating Prospective Payment, MS–DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and Critical Access Hospital (CAH) Issues.

Emily Lipkin, (410) 786–3633 and Jim Mildenberger, (410) 786–4551, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Emily Forrest, (202) 205–1922, Market-Based Data Collection and Market-Based MS–DRG Relative Weight Methodology Issues.

Allison Pompey, (410) 786–2348, New Technology Add On Payments and New COVID–19 Treatments Add-on Payments Issues.

Mady Hue, (410) 786–4510, and Andrea Hazeley, (410) 786–3543, MS–DRG Classifications Issues.

Mollie Knight, (410) 786–7948, and Bridget Dickensheets, (410) 786–8670, Rebasing and Revising the Hospital Market Baskets Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, (410) 786–0110, Frontier Community Health Integration Project Demonstration Issues.

Pamela Brown, *pamela.brown@cms.hhs.gov*, Hospital Readmissions Reduction Program—Administration Issues.

Jim Poyer, *james.poyer@cms.hhs.gov*, Hospital Readmissions Reduction Program—Readmissions—Measures Issues.

Jennifer Tate, *jennifer.tate@cms.hhs.gov*, Hospital-Acquired Condition Reduction Program—Administration Issues.

Yuling Li, (410) 786–8421, Hospital-Acquired Condition Reduction Program—Measures Issues.

Julia Venanzi, *julia.venanzi@cms.hhs.gov*, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Administration Issues

Katrina Hoadley, *katrina.hoadley@cms.hhs.gov*, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Annie Hollis, *annie.hollis@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting—Administration Issues.

Katrina Hoadley, *katrina.hoadley@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting Program-Measure Issues

Christy Hughes, (410) 786–5662, Long-Term Care Hospital Quality Reporting Program—Data Reporting Issues.

Jessica Warren, *jessica.warren@cms.hhs.gov* and Elizabeth Holland, *elizabeth.holland@cms.hhs.gov*, Promoting Interoperability Programs.

Candace Anderson, (410) 786–1553, Medicaid Enrollment of Medicare Providers and Suppliers for Purposes of Processing Claims for Cost-Sharing for Services Furnished to Dually Eligible Beneficiaries.

Naseem Tarmohamed, (410) 786–0814, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Shared Savings Program.

SUPPLEMENTARY INFORMATION:

Tables Available Through the Internet on the CMS Website

The IPPS tables for this FY 2022 final rule are available through the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2022 IPPS Final rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2022 final rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1752–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this FY 2022 IPPS/LTCH PPS final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel at (410) 786–4552.

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2022 IPPS/LTCH PPS final rule makes payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it makes payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This final rule also makes policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this FY 2022 final rule, we are continuing policies to address wage index disparities impacting low wage index hospitals. We are finalizing our implementation of Section 9831 of the American Rescue Plan Act of 2021, which permanently established the imputed floor wage index policy. In addition, we are finalizing the regulations implemented in CMS–1762–IFC (86 CFR 24735–24739), which allowed hospitals with a rural redesignation under the Act to reclassify through the MGCRB using the rural reclassified area as the geographic area in which the hospital is located. This final rule includes policies related to new technology add-on payments. We are also finalizing our proposal to repeal the collection of market-based rate information on the Medicare cost report and the market-based MS–DRG relative weight methodology.

We are establishing new requirements and revising existing requirements for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

We are providing estimated and newly established performance standards for the Hospital Value-Based Purchasing (VBP) Program, and updated policies for the Hospital Readmissions Reduction Program, Hospital Inpatient Quality Reporting (IQR) Program, Hospital VBP Program, Hospital-Acquired Condition (HAC) Reduction Program, Long-Term Care Hospital Quality Reporting Program (LTCH QRP), and the PPS-Exempt Cancer Hospital Reporting (PCHQR) Program. Additionally, due to the impact of the COVID–19 PHE on measure data used in our value-based purchasing programs, we are finalizing our proposal to suppress several measures in the Hospital VBP, HAC Reduction, and Hospital Readmissions Reduction Programs. As a result of these measure suppressions for the Hospital VBP Program we are also implementing a special scoring methodology for FY 2022 that results in a value-based incentive payment amount that matches the 2-percent reduction to the base operating DRG payment amount.

We note that the FY 2022 IPPS/LTCH PPS proposed rule included our proposals related to the implementation of the provisions of the Consolidated Appropriations Act (CAA) of 2021 related to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs. Please refer to the proposed rule (86 FR 25502 through 25524) for additional background information on these proposals. Due to the number and nature of the comments that we received on the implementation of sections 126, 127 and 131 of the CAA of 2021 relating to payments to hospitals for direct GME and IME costs, we will address public comments associated with these issues in future rulemaking.

In addition, we note that the FY 2022 IPPS/LTCH PPS proposed rule included our proposals related to the organ acquisition payment policy for transplant hospitals, donor community hospitals and organ procurement organizations. Please refer to the proposed rule (86 FR 25656 through 25676) for additional background information on these proposals. Due to the number and nature of the comments that we received on the organ acquisition payment policy proposals we will address public comments associated with these issues in future rulemaking.

Under various statutory authorities, we either discuss continued program implementation or are making changes to the Medicare IPPS, to the LTCH PPS, other related payment methodologies and programs for FY 2022 and subsequent fiscal years, and other policies and provisions included in this rule. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the BBRA (Public Law (Pub. L.) 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1886(a)(4) of the Act, which specifies that costs of approved

educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.

- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions.
- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(5) of the Act, which requires the Secretary to reduce by two percentage points the annual update to the standard Federal rate for discharges for a long-term care hospital (LTCH) during the rate year for LTCHs that do not submit data in the form, manner, and at a time, specified by the Secretary.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.
- Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.
- Section 1899 of the Act which established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers and suppliers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B.
- Section 1902(kk)(3) of the Act, as amended by section 6401(b) of the Affordable Care Act, which mandates that states require providers and suppliers to comply with the same disclosure requirements established by the Secretary under section 1866(j)(5) of the Act.
- Section 2107(e)(1) of the Act, as amended by section 6401(c) of the Affordable Care Act, which makes the requirements of section 1902(kk) of the Act, including the disclosure requirements, applicable to CHIP.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this final rule. In general, these major provisions are being finalized as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the changes in this final rule is presented in section I.D. of the preamble of this final rule.

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. The FY 2014 through FY 2017 adjustments represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.) Therefore, for FY 2022, we are making an adjustment of +0.5 percent to the standardized amount.

b. Extension of the New COVID–19 Treatments Add-on Payment (NCTAP)

In response to the COVID–19 PHE, we established the New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71157 and 71158). We believe that as drugs and biological products become available and are authorized for emergency use or approved by Food and Drug Administration (FDA) for the treatment

of COVID–19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE. Therefore, effective for discharges occurring on or after November 2, 2020 and until the end of the PHE for COVID–19, CMS established the NCTAP.

We anticipate that there might be inpatient cases of COVID–19, beyond the end of the PHE, for which payment based on the assigned MS–DRG may not adequately reflect the additional cost of new COVID–19 treatments. In order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE, we believe that the NCTAP should remain available for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends (for example, until September 30, 2022). After review of public comments received, and for the reasons discussed in section II.F. of the preamble of this final rule, we are finalizing to extend the NCTAP through the end of the fiscal year in which the PHE ends for all eligible products, including those approved for new technology add-on payments for FY 2022, with any new technology add-on payment reducing the amount of the NCTAP.

c. Use of FY 2020 or FY 2019 Data in the FY 2022 IPPS and LTCH PPS Ratesetting

For the IPPS and LTCH PPS ratesetting, our longstanding goal is always to use the best available data overall. In section I.F. of the preamble of this final rule, we discuss our analysis of the best available data for use in the development of this FY 2022 IPPS/LTCH PPS final rule given the potential impact of the public health emergency (PHE) for the Coronavirus Disease (COVID–19). As discussed in section I.F. of the preamble of this final rule, we are using the FY 2019 data, such as the FY 2019 MedPAR file, for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE, primarily in that the utilization of inpatient services reflect generally markedly different utilization for certain types of services in FY 2020 than would have been expected in the absence of the PHE.

d. Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated that this policy will be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Therefore, for FY 2022, we are continuing the low-wage index hospital policy, and are also applying this policy in a budget neutral manner by applying an adjustment to the standardized amounts.

e. Implementation of Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) Imputed Floor Wage Index Policy for All-Urban States

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) amended section 1886(d)(3)(E) of the Act (42 U.S.C. 1395ww(d)(3)(E)) to establish a minimum area wage index for hospitals in all-urban States. Specifically, section 1886(d)(3)(E)(iv) of the Act (as added by section 9831(a)(2) of Pub. L. 117–2) reinstates the imputed floor wage index policy for all-urban States effective for discharges on or after October 1, 2021 (FY 2022) with no expiration date using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018. Furthermore, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. We refer readers to section III.G.2. of this final rule for a summary of the provisions of section 9831 of Public Law 117–2 that we are implementing in this final rule.

f. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, Medicare DSHs receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this final rule, we are updating our estimates of the three factors used to determine uncompensated care payments for FY 2022. We are also continuing to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in the calculation of Factor 2. Consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule for FY 2022 and subsequent fiscal years, we are using a single year of data on uncompensated care costs from Worksheet S–10 of the FY 2018 cost reports to calculate Factor 3 in the FY 2022 methodology for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. For IHS and Tribal hospitals and Puerto Rico hospitals we are finalizing our proposal to continue to use the low-income insured days proxy to calculate Factor 3 for these hospitals for FY 2022. We are also finalizing certain methodological changes for calculating Factor 3 for FY 2022.

g. Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board (MGCRB)

In May 10, 2021 **Federal Register** (86 FR 24735), concurrent with the FY 2022 IPPS/LTCH PPS proposed rule, we published an interim final rule with comment period (IFC) (CMS–1762–IFC) that amended our current regulations to allow hospitals with a rural redesignation under the Act to reclassify through the Medicare MGCRB using the rural reclassified area as the geographic area in which the hospital is located. These regulatory changes align our policy with the decision in *Bates County Memorial Hospital* v. *Azar*, effective with reclassifications beginning with fiscal year (FY) 2023. We respond to the public comments on CMS–1762–IFC in this final rule, and finalize the regulatory changes made therein.

h. Reduction of Hospital Payments for Excess Readmissions

We are making changes to policies for the Hospital Readmissions Reduction Program, which was established under section 1886(q) of the Act, as amended by section 15002 of the 21st Century

Cures Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. In this FY 2022 IPPS/LTCH PPS final rule, we are finalizing the following policies: (1) To adopt a cross-program measure suppression policy for the duration of the public health emergency for COVID–19; (2) to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) for the FY 2023 program year; (3) to modify the remaining five condition-specific readmission measures to exclude COVID–19 diagnosed patients from the measure denominators, beginning with the FY 2023 program year; (4) to use the MedPAR data that aligns with the applicable period for FY 2022; (5) to automatically adopt the use of MedPAR data corresponding to the applicable period beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary; and (6) to update the regulatory text to reflect that our Hospital Compare website has been renamed and is now referred to as Care Compare. We are clarifying our Extraordinary Circumstances Exceptions (ECE) policy, and we also requested public comment on opportunities to advance health equity through possible future stratification of results by race and ethnicity for condition/procedure-specific readmission measures and by expansion of standardized data collection to additional social factors, such as language preference and disability status. We also sought comment on mechanisms of incorporating other demographic characteristics into analyses that address and advance health equity, such as the potential to include administrative and self-reported data to measure co-occurring disability status.

i. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this final rule, we are finalizing our proposals to: (1) Establish a measure suppression policy for the duration of the public health emergency for COVID–19; (2) suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), Medicare Spending Per Beneficiary (MSPB), and five Healthcare-Associated Infection (HAI) measures, for the FY 2022 program year; and (3) suppress the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia (PN) Hospitalization (MORT–30–PN) measure for the FY 2023 program year. We are also finalizing our proposal to revise the scoring and payment methodology for the FY 2022 program year such that hospitals will not receive Total Performance Scores. We believe that awarding a TPS to any hospital based off the remaining measures that are not suppressed would not result in a fair national comparison and, as a result, are not awarding a TPS to any hospital for the FY 2022 program year. Instead, we are finalizing our proposal to award each hospital a payment incentive multiplier that results in a value-based incentive payment that is equal to the amount withheld for the fiscal year (2 percent). We are finalizing our proposal to remove the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure beginning with FY 2023 because the costs associated with the measure outweigh the benefit of its use in the program. We are also finalizing our proposal to update the baseline periods for certain measures affected by the ECE granted in response to the COVID–19 PHE and making a technical update to our terminology used in the Hospital VBP Program regulations.

j. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals, effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to hospitals that rank in the worst-performing quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. In this FY 2022 IPPS/LTCH PPS final rule, we are: (1) Clarifying our ECE policy; (2) finalizing our proposal to adopt a cross-program measure suppression policy for the duration of the public health emergency for COVID–19; (3) finalizing our proposal to apply that measure suppression policy to suppress certain program data from FY 2022, FY 2023, and FY 2024 HAC Reduction Programs; and (4) finalizing our proposal to update the regulatory text to reflect that the *Hospital Compare* website has been renamed and is now referred to as *Care Compare.*

k. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that fiscal year.

In this FY 2022 IPPS/LTCH PPS final rule, we are making several changes. We are finalizing the adoption of five new measures: (1) A new structural measure—Maternal Morbidity Structural Measure—beginning with a shortened reporting period from October 1, 2021 through December 31, 2021 affecting the CY 2021 reporting period/FY 2023 payment determination; (2) the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure in a stepwise fashion, beginning with a voluntary reporting period from July 1, 2022 through June 30, 2023, and followed by mandatory reporting from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years; (3) the COVID–19 Vaccination Coverage among Health Care Personnel (HCP) measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination and with quarterly reporting beginning with the FY 2024 payment determination and for subsequent years; and two medication-related adverse event eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination; (4) Hospital Harm-Severe Hypoglycemia eCQM (NQF #3503e); and (5) Hospital Harm-Severe Hyperglycemia eCQM (NQF #3533e).

We are also finalizing the removal of three measures: (1) Exclusive Breast Milk Feeding (PC–05) (NQF #0480) beginning with the FY 2026 payment determination; (2) Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) (NQF #0497) beginning with the FY 2026 payment determination; and (3) the Discharged on Statin Medication eCQM (STK–06)

(NQF #0439), beginning with the FY 2026 payment determination. We are not finalizing our proposals to remove the following two measures: (1) Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04); and (2) Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK–03) (NQF #0436).

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070), we requested comment from stakeholders on the potential future development and inclusion of two measures: (1) A mortality measure for patients admitted with COVID–19; and (2) a patient-reported outcomes measure following elective total hip and/or total knee arthroplasty (THA/TKA). We also requested comment from stakeholders on ways we can leverage measures to address gaps in existing health equity generally as well as comment on: (1) Potential future confidential stratified reporting for the Hospital-Wide All-Cause Unplanned Readmission (HWR) measure using both dual eligibility and race/ethnicity; and (2) potential future reporting of a structural measure to assess the degree of hospital leadership engagement in health equity performance data. We also requested feedback across programs on potential actions and priority areas that would enable the continued transformation of our quality measurement toward greater digital capture of data and use of the FHIR standard.

In addition, we are finalizing our proposal that beginning with the CY 2023 reporting period/FY 2025 payment determination, hospitals will be required to use certified technology that has been updated consistent with the 2015 Edition Cures Update and clarifying that certified technology must support the reporting requirements for all available eCQMs. We also are finalizing our provision that hybrid measures comply with the same certification requirements as eCQMs, specifically that EHR technology must be certified to the 2015 Edition Cures Update. We are revising 42 CFR 412.140(a)(2) and 42 CFR 412.140(e)(2)(iii) to replace the terms ''Security Administrator'' and ''System Administrator'' with the term ''security official'' in alignment with other CMS quality programs. Due to an updated URL for the QualityNet website from *QualityNet.org* to *QualityNet.cms.gov*, we are also revising Hospital IQR Program regulations at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i) to reflect updates to the QualityNet website. Lastly, we are finalizing our proposal to extend the effects of the educational review process for chart-abstracted measures beginning with validations affecting the FY 2024 payment determination.

l. PPS-Exempt Cancer Hospital Quality Reporting Program

Section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

In this final rule, we are removing the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) measure beginning with the FY 2024 program year, adopting the COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the FY 2023 program year, making a technical update to the terminology we use in the program, and codifying existing PCHQR Program policies in our regulations.

m. Medicare Promoting Interoperability Program

For purposes of reducing the burden on eligible hospitals and CAHs, we are making several changes to the Medicare Promoting Interoperability Program. Specifically, we are: (1) Continuing the EHR reporting period of a minimum of any continuous 90-day period for new and returning eligible hospitals and CAHs for CY 2023 and increasing the EHR reporting period to a minimum of any continuous 180-day period for new and returning eligible hospitals and CAHs for CY 2024; (2) maintaining the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing its available bonus from 5 points to 10 points for the EHR reporting period in CY 2022; (3) adding a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation to the HIE objective as an optional alternative to the two existing measures beginning with the EHR reporting period in CY 2022; (4) requiring reporting a ''yes'' on four of the existing Public Health and Clinical Data Exchange Objective measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) or requesting the applicable exclusion(s); (5) adding a new measure to the Protect Patient Health Information objective that requires eligible hospitals and CAHs to attest to having completed an annual assessment of SAFER Guides beginning with the EHR reporting period in CY 2022; (6) removing attestation statements 2 and 3 from the Promoting Interoperability Program's prevention of information blocking requirement; (7) increasing the minimum required score for the objectives and measures from 50 points to 60 points (out of 100 points) in order to be considered a meaningful EHR user; and (8) adopting two new eCQMs to the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2023, in addition to removing three eCQMs from the measure set beginning with the reporting period in CY 2024, which updates are in alignment with the eCQM updates being finalized for the Hospital IQR Program. We are amending our regulation texts as necessary to incorporate several of these changes. We are not finalizing our proposal to remove the Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK–03) (NQF #0436) in alignment with the Hospital IQR Program. We are also not finalizing our proposal to modify the Provide Patients Electronic Access to Their Health Information measure by requiring eligible hospitals and CAHs to ensure that patient health information remains available to the patient (or patient-authorized representative). We will consider the feedback we received for future rulemaking.

n. Repeal of Market-Based Data Collection and Market-Based MS–DRG Relative Weight Methodology

As discussed in section V.L. of the preamble of this final rule, we are finalizing our proposal, without modification, to repeal the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021. We are also finalizing our proposal, without modification, to repeal the market-based MS–DRG relative weight methodology adopted for calculating the MS–DRG relative weights effective in FY 2024, and to continue using the existing cost-based methodology for calculating the MS–DRG relative weights for FY 2024 and subsequent fiscal years. Lastly, we solicited comment on alternative approaches or data sources that could be used in Medicare fee-for-service (FFS) ratesetting. We will continue to consider these comments as applicable.

o. Medicare Shared Savings Program

We are making changes to policies for the Shared Savings Program, which was established under section 1899 of the Act, to allow eligible ACOs participating in the BASIC track's glide path the option to elect to forgo automatic advancement along the glide path's increasing levels of risk and potential reward for performance year (PY) 2022. Under the policy we are adopting in this final rule, prior to the automatic advancement for PY 2022, an eligible ACO may elect to remain in the same level of the BASIC track's glide path in which it participated during PY 2021. For PY 2023, an ACO that elects this advancement deferral option will be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2023 if it had advanced automatically to the required level for PY 2022 (unless the ACO elects to advance more quickly before the start of PY 2023).

3. Summary of Costs and Benefits

The following table provides a summary of the costs, savings, benefits associated with the major provisions described in section I.A.3. of the preamble of this final rule.

BILLING CODE 4120–01–P

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Adjustment for MS-DRG Documentation and Coding Changes	Section 414 of the MACRA replaced the single positive adjustment we intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percentage point positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percentage point by section 15005 of the 21st Century Cures Act.) For FY 2022, we are making an adjustment of +0.5 percentage point to the standardized amount consistent with the MACRA.
Changes to the New COVID-19 Treatments Add-on Payment	In response to the COVID-19 PHE, CMS established the New COVID-19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID-19 cases that meet certain criteria (85 FR 71155). We anticipate inpatient cases of COVID-19 beyond the end of the PHE for which payment based on the assigned MS-DRG may not adequately reflect the additional cost of new COVID-19 treatments. In order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE, we believe that the NCTAP should remain available for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends (for example, until September 30, 2022). Therefore, after consideration of comments received, we are extending the NCTAP for all eligible products through the end of the fiscal year in which the PHE ends (for example, until September 30, 2022), including for technologies/cases eligible for new technology add-on payments, with the new technology add-on payment reducing the amount of the NCTAP. On one extreme, if all of the new COVID–19 treatments decrease the net cost of hospitalizations (for example, due to shortened lengths of stay), including the cost of the new treatment, below the Medicare payment for discharges after the end of the PHE and through the end of the fiscal year in which the PHE ends, then there would be no NCTAP made and no additional cost to the Medicare program as a result of this proposed extension. On the other extreme, if all of the new COVID–19 treatments result in the net cost of hospitalizations that exceed the outlier threshold (for example, due to the cost of the new treatment) for discharges after the end of the PHE and through the end of the fiscal year in which the PHE ends, the cost to the Medicare program would be the sum over all such NCTAP cases of 0.65 times the outlier threshold for each case. Given it is unknown what the cost and utilization of inpatient stays using these new treatments will be, this is a cost but is not estimable. Therefore, it is not possible to quantify the impact of the extension of the NCTAP.
Implementation of Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) Imputed Floor Wage Index Policy for All-Urban States	As discussed in section III.G.2. of the preamble of this final rule, we are implementing section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) which reinstates the imputed floor wage index policy for all-urban States effective for discharges on or after October 1, 2021 (FY 2022) with no expiration date using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018. Furthermore, section 1886(d)(3)(E)(iv)(III) of the Act (as added by section 9831(a)(2) of the American Rescue Plan Act of 2021) provides that the imputed floor wage index shall not be applied in a budget neutral manner. We estimate that our proposed implementation of section 9831 of the American Rescue Plan Act of 2021 will result in an estimated cost of approximately $0.2 billion for FY 2022.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care	For FY 2022, we are updating our estimates of the three factors used to determine uncompensated care payments. We are continuing to use uninsured estimates produced by OACT as part of the development of the NHEA in conjunction with more recently available data that takes into consideration the effects of the COVID-19 pandemic in the calculation of Factor 2. Consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule for FY 2022 and subsequent fiscal years, we are using a single year of data on uncompensated care costs from Worksheet S–10 for FY 2018 to determine Factor 3 for FY 2022 for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. To determine the amount of uncompensated care for purposes of calculating Factor 3 for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we are continuing to use data regarding low-income insured days for FY 2013. We project that the amount available to distribute as payments for uncompensated care for FY 2022 will decrease by approximately $1.4 billion, as compared to our estimate of the uncompensated care payments that will be distributed in FY 2021. The uncompensated care payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges.
Update to the IPPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this final rule, acute care hospitals are estimated to experience an increase of approximately $2.3 billion in FY 2022, including operating (including increased payments as a result of the imputed floor provision in section 9831 of the American Rescue Plan Act of 2021), capital, and new technology changes, as modeled for this final rule.
Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this final rule, based on the best available data for the 363 LTCHs in our database, we estimate that the changes to the payment rates and factors that we present in the preamble of and Addendum to this final rule, which reflect the update to the LTCH PPS standard Federal payment rate for FY 2022, will result in an estimated increase in payments in FY 2022 of approximately $42 million.
Changes to the Hospital Readmissions Reduction Program	For FY 2022 and subsequent years, DRG reductions in payments are based on a hospital's risk-adjusted readmission rate during the performance period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. Overall, in this final rule, we estimate that 2,500 hospitals will have their base operating DRG payments reduced by their determined estimated FY 2022 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately $521 million in FY 2022.
Value-Based Incentive Payments under the Hospital VBP Program	We estimate that there will be no net financial impact to the Hospital VBP Program for the FY 2022 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. Specifically for the FY 2022 program year, after applying the measure suppressions and special scoring policy, the estimated amount of base operating MS-DRG payment amount reductions and payback to hospitals is approximately $1.9 billion.
Changes to the HAC Reduction Program	A hospital's Total HAC Score and its ranking in comparison to other hospitals in any given year depend on several different factors. We are making no changes to the scoring methodology, which will continue to use the Winsorized z-score and equal measure weights approaches to determine the worst-performing quartile of hospitals. Any significant impact due to the HAC Reduction Program changes for FY 2022, including which hospitals will receive the adjustment, will depend on the actual experience of hospitals in the Program. For example, a hospital with poor performance during CY 2020 may move out of the worst-performing quartile status (that is, not receive a payment reduction) due to the measure suppression policy. In turn, this would lead to another hospital moving into the worst-performing quartile status. In a typical year, approximately 18 percent of hospitals experience a change in worst-performing quartile status from one year to the next. Preliminary analysis indicates the percentage of hospitals experiencing a change in worst-performing quartile status to be 17.2 percent due to the measure suppression policy. We refer readers to section IX.I.3.c. of the preamble of this final rule.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Changes to the Hospital Inpatient Quality Reporting (IQR) Program	Across 3,300 IPPS hospitals, we estimate that our changes for the Hospital IQR Program in this final rule will result in a total information collection burden increase of 2,475 hours associated with our policies and updated burden estimates and a total cost increase of approximately $101,475 across a 4-year period from the CY 2022 reporting period/FY 2024 payment determination through the CY 2025 reporting period/FY 2027 payment determination.
Changes to the Medicare and Promoting Interoperability Program	Based on updated wage rates for 2019 from the Bureau of Labor Statistics, and an amended hourly staff usage from that of a lawyer to a medical records and health information technician role, we estimate that the finalized changes will result in a net decrease of $607,893 for the annual information collection burden (total cost) in CY 2022.
Market-Based MS-DRG Relative Weight Policy – Repeal	In section V.L. of the preamble of this final rule, we finalize our proposal to repeal the requirement that hospitals report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS-DRG, for cost reporting periods ending on or after January 1, 2021. We are also finalizing our proposal to repeal the market-based MS-DRG relative weight methodology adopted for calculating the MS-DRG relative weights effective in FY 2024. We previously estimated total annual burden hours for this policy and refer readers to (85 FR 59015) for further analysis of this estimate.
Changes to the Medicare Shared Savings Program	In section I.H.12 of Appendix A of this final rule, we describe the estimated impacts of our changes to the Shared Savings Program to extend the flexibility for eligible ACOs to elect to "freeze" their participation level along the BASIC track's glide path for PY 2022. The net effect of offering this flexibility is estimated to be a $90 million reduction in Federal spending, with the reduction ranging from $50 to $140 million.

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B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2022. For discharges occurring on or after October 1, 2007, but before October 1, 2022, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included

along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation Implemented in This Final Rule

1. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10) specifies a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. These adjustments follow the recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring from FYs 2014 through 2017 to fully offset $11 billion, in accordance with section 631 of the ATRA. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.

2. The American Rescue Plan Act of 2021 (Pub. L. 117–2)

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) amended section 1886(d)(3)(E) of the Act (42 U.S.C. 1395ww(d)(3)(E)) to establish a minimum area wage index for hospitals in all-urban States. Specifically, section 1886(d)(3)(E)(iv) of the Act (as added by section 9831(a)(2) of Pub. L. 117–2) reinstates the imputed floor wage index policy for all-urban states effective for discharges on or after October 1, 2021 (FY 2022) with no expiration date using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018.

D. Issuance of Proposed and Interim Final Rulemakings

1. FY 2022 IPPS/LTCH PPS Proposed Rule

In the FY 2022 IPPS/LTCH PPS proposed rule appearing in the May 10, 2021 **Federal Register** (86 FR 25070), we set forth proposed payment and policy changes to the Medicare IPPS for FY 2022 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2022.

The following is a general summary of the changes that we proposed to make.

a. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we include—

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2022.
- Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2022 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2022 status of new technologies approved for add-on payments for FY 2022, a presentation of our evaluation and analysis of the FY 2022 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting) for applications not submitted under an alternative pathway, and a discussion of the proposed status of FY 2022 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.
- A proposal to extend the New COVID–19 Treatments Add-on Payment (NCTAP) through the end of the fiscal year in which the PHE ends for certain products and discontinue NCTAP for products approved for new technology add-on payments in FY 2022.

b. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of the proposed rule, we proposed to revise to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but were not limited to, the following:

- The proposed FY 2022 wage index update using wage data from cost reporting periods beginning in FY 2018.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for

FY 2022 based on the 2019 Occupational Mix Survey.

- Proposed application of the rural floor and the frontier State floor, and continuation of the low wage index hospital policy.
- Proposed implementation of the imputed floor wage index policy for all-urban States under section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2).
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed revisions to the regulations at § 412.278 regarding the Administrator's Review of MGCRB decisions.
- Proposed changes to rural reclassification cancellation requirements at § 412.103(g).
- Proposed adjustment to the wage index for acute care hospitals for FY 2022 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Proposed labor-related share for the proposed FY 2022 wage index.

c. Proposed Rebasing and Revising of the Hospital Market Baskets

In section IV. of the preamble of the proposed rule, we proposed to rebase and revise the hospital market baskets for acute care hospitals and update the labor-related share.

d. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of the proposed rule, we discussed proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed inpatient hospital update for FY 2022.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- The statutorily required IME adjustment factor for FY 2022.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- Proposed requirements for payment adjustments under the Hospital Readmissions Reduction Program for FY 2022.
- The provision of estimated and newly established performance standards for the calculation of value-based incentive payments, as well as a proposal to suppress multiple measures and provide net-neutral payment adjustments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2022.
- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2022.
- Proposed revisions to the regulations regarding the counting of days associated with section 1115 demonstration projects in the Medicaid fraction.
- Proposals to implement provisions of the Consolidated Appropriations Act relating to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs.
- Proposed repeal of the market-based data collection requirement and market-based MS–DRG relative weight methodology

e. Proposed FY 2022 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble to the proposed rule, we discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2022.

f. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of the proposed rule, we discussed the following:

- Proposed changes to payments to certain excluded hospitals for FY 2022.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

g. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of the proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2022.

h. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of the proposed rule, we addressed the following:

- We requested information on CMS's future plans to define digital quality measures (dQMs) in CMS Hospital Quality Programs and on CMS' continued efforts to close the health equity gap in CMS Hospital Quality Programs.
- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- Proposed changes to the requirements under the LTCH Quality Reporting Program (QRP). We also sought information on CMS's future plans to define digital quality measures (dQMs) for the LTCH QRP and on CMS' continued efforts to close the health equity gap.
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

i. Other Proposals Included in the Proposed Rule

Section X. of the preamble of the proposed rule included the following proposals:

- Proposed changes pertaining to Medicaid enrollment of Medicare-enrolled providers and suppliers to 42 CFR part 455.410 and request for comment on provider experiences where State Medicaid agencies apply the Medicaid payment and coverage rules to a claim for a Medicare service rather than adjudicating the claim for Medicare cost-sharing liability.
- Proposed changes pertaining to Medicare's share of organ acquisition costs transplanted into Medicare beneficiaries and the charges for services provided to cadaveric organ donors by donor community hospitals and transplants hospitals.
- Proposed changes pertaining to the Shared Savings Program that would allow eligible ACOs participating in the BASIC track's glide path to maintain their current level of participation for PY 2022.

j. Other Provisions of the Proposed Rule

Section XI. of the preamble to the proposed rule included our discussion of the MedPAC Recommendations.

Section XII. of the preamble to the proposed rule includes the following:

- A descriptive listing of the public use files associated with the proposed rule.
- The collection of information requirements for entities based on our proposals.
- Information regarding our responses to public comments.

k. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum to the proposed rule, we set

forth proposed changes to the amounts and factors for determining the proposed FY 2022 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum to the proposed rule, we addressed the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2022 for certain hospitals excluded from the IPPS.

l. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2022 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2022. We are proposing to establish the adjustments for the wage index, labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

m. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, PCHs and other entities.

n. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2022 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

o. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2021 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2021 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at: *http://www.medpac.gov*.

2. Medicare Geographic Classification Review Board (MGCRB) Interim Final Rule With Comment Period

In the interim final rule with comment period appearing in the May 10, 2021 **Federal Register** (86 FR 25735) (hereinafter referred to as CMS–1762–IFC), we implemented regulations which allowed hospitals with a rural redesignation under the section XXXX of the Act to reclassify through the Medicare Geographic Classification Review Board (MGCRB) using the rural reclassified area as the geographic area in which the hospital is located.

E. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO *http://pacioproject.org/*) to facilitate collaboration with industry stakeholders to develop FHIR standards. These standards could support the exchange and reuse of patient assessment data derived from the Minimum Data Set (MDS), Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), LTCH Continuity Assessment Record and Evaluation (CARE Data Set (LCDS), Outcome and Assessment Information Set (OASIS), and other sources. The PACIO Project has focused on FHIR implementation guides for functional status, cognitive status and new use cases on advance directives and speech language pathology. We encourage post-acute care (PAC) provider and health information technology (IT) vendor participation as the efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as the authoritative resource for PAC assessment data elements and their associated mappings to health IT standards, such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED). The DEL furthers CMS' goal of data standardization and interoperability. These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data; supporting provider exchange of electronic health information for care coordination, person-centered care; and supporting real-time, data driven, clinical decision-making. Standards in the Data Element Library (*https://del.cms.gov/DELWeb/pubHome*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2021 ISA is available at *https://www.healthit.gov/isa*.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. The Cures Act includes a trusted exchange framework and common agreement (TEFCA) provision [1] that will enable the nationwide exchange of electronic health information across health information networks and provide an important way to enable bi-directional health information exchange in the future. For more information on current developments related to TEFCA, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement* and *https://rce.sequoiaproject.org/*.

The ONC final rule entitled ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (85 FR 25642) published in the May 1, 2020 **Federal Register**, (hereinafter referred to as ''ONC Cures Act Final Rule'')

[1] ONC, Draft 2 Trusted Exchange Framework and Common Agreement, *https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf*.

implemented policies related to information blocking as authorized under section 4004 of the 21st Century Cures Act. Information blocking is generally defined as a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the HHS Secretary as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information. For a health care provider (as defined in 45 CFR 171.102), the definition of information blocking (see 45 CFR 171.103) specifies that the provider knows that the practice is unreasonable, as well as likely to interfere with access, exchange, or use of electronic health information.[2] To deter information blocking, health IT developers of certified health IT, health information networks and health information exchanges whom the HHS Inspector General determines, following an investigation, have committed information blocking, are subject to civil monetary penalties of up to $1 million per violation. Appropriate disincentives for health care providers need to be established by the Secretary through rulemaking. Stakeholders can learn more about information blocking at *https://www.healthit.gov/curesrule/final-rule-policy/information-blocking*. ONC has posted information resources including fact sheets (*https://www.healthit.gov/curesrule/resources/fact-sheets*), frequently asked questions (*https://www.healthit.gov/curesrule/resources/information-blocking-faqs*), and recorded webinars (*https://www.healthit.gov/curesrule/resources/webinars*).

We invite providers to learn more about these important developments and how they are likely to affect LTCHs.

F. Use of FY 2020 or FY 2019 Data in the FY 2022 IPPS and LTCH PPS Ratesetting

We primarily use two data sources in the IPPS and LTCH PPS ratesetting: Claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital claims for discharges in a fiscal year. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available MedPAR data would be the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. For FY 2022 ratesetting, under ordinary circumstances, the best available data would be the FY 2020 MedPAR file. The cost report data source is the Medicare hospital cost report data files from the most recent quarterly HCRIS release. For example, ordinarily, the best available cost report data used in relative weight calculations would be based on the cost reports beginning 3 fiscal years prior to the fiscal year that is the subject of the rulemaking. For the FY 2022 ratesetting, under ordinary circumstances, that would be the FY 2019 cost report data from HCRIS, which would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25086 through 25090), we discussed that the FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset both contain data significantly impacted by the COVID–19 PHE, primarily in that the utilization of inpatient services was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. Accordingly, we questioned whether these data sources are the best available data to use for the FY 2022 ratesetting. In the proposed rule, we identified two factors for assessing whether these data sources represent the best available data. The first factor is to what extent the FY 2019 data from before the COVID–19 PHE is a better overall approximation of FY 2022 inpatient experience (for example, whether the share of total inpatient utilization for elective surgeries will be more similar to FY 2019 than to FY 2020), or alternatively, to what extent the FY 2020 data which include the COVID–19 PHE time period is a better overall approximation of FY 2022 inpatient experience (for example, whether the share of total inpatient utilization for respiratory infections will be more similar to FY 2020 than to FY 2019). The second factor is to what extent the decision to use the FY 2019 or FY 2020 data differentially impacts the FY 2022 IPPS ratesetting.

In the proposed rule, in order to help assess likely inpatient utilization in FY 2022, we examined the trend in the number of COVID–19 vaccinations in the United States as reported to the Centers for Disease Control (CDC) (see *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html*, accessed April 16, 2021).

The U.S. COVID–19 Vaccination Program began December 14, 2020. As of April 15, 2021, 198.3 million vaccine doses had been administered. Overall, about 125.8 million people, or 37.9 percent of the U.S. population, had received at least one dose of vaccine as of this date. About 78.5 million people, or 23.6 percent of the U.S. population had been fully vaccinated.[3] As of April 15, the 7-day average number of administered vaccine doses reported to CDC per day was 3.3 million, a 10.3 percent increase from the previous week. As of April 15, 80 percent of people 65 or older had received at least one dose of vaccine; 63.7 percent were fully vaccinated. Nearly one-half (48.3 percent) of people 18 or older had received at least one dose of vaccine; 30.3 percent were fully vaccinated. Nationally, COVID–19-related emergency department visits as well as both hospital admissions and current hospitalizations had risen among patients ages 18 to 64 years in recent weeks, but emergency department visits and hospitalizations among people ages 65 years and older had decreased, likely demonstrating the important role vaccination plays in protecting against COVID–19.

As indicated by the CDC, COVID–19 vaccines are effective at preventing COVID–19.[4] For example, a CDC report on the effectiveness of the Pfizer-BioNTech and Moderna COVID–19 vaccines when administered in real-world conditions found that after being fully vaccinated with either of these vaccines a person's risk of infection is reduced by up to 90 percent. With respect to inpatient utilization in FY 2020, in the proposed rule we stated our belief that COVID–19 and the risk of disease were drivers of the different utilization patterns observed. Therefore, the continuing rapid increase in vaccinations coupled with the overall effectiveness of the vaccines led us to conclude based on the information

[2] For other types of actors (health IT developers of certified health IT and health information network or health information exchange, as defined in 45 CFR 171.102), the definition of ''information blocking'' (see 45 CFR 171.103) specifies that the actor ''knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information.''

[3] People who are fully vaccinated (formerly receiving 2 doses) represents the number of people who have received the second dose in a two-dose COVID–19 vaccine series or one dose of the single-dose J&J/Janssen COVID–19 vaccine.

[4] Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA–1273 COVID–19 Vaccines in Preventing SARS–CoV–2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers—Eight U.S. Locations, December 2020–March 2021, available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_e&ACSTrackingID=USCDC_921-DM53321&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2070%2C%20March%2029%2C%202021&deliveryName=USCDC_921-DM53321*, accessed April 2, 2021).

available at the time of the proposed rule that there will be significantly lower risk of COVID–19 in FY 2022 and fewer hospitalizations for COVID–19 for Medicare beneficiaries in FY 2022 than there were in FY 2020. This called into question the applicability of inpatient data from FY 2020 to the FY 2022 time period for hospitals paid under the IPPS and LTCH PPS.

In the proposed rule, we also reviewed CDC guidance to healthcare facilities during the COVID–19 PHE (see *https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html*). In its most recent guidance available at the time of the proposed rule, the CDC described how the COVID–19 pandemic has changed how health care is delivered in the United States and has affected the operations of healthcare facilities. Effects cited by the CDC include increases in patients seeking care for respiratory illnesses, patients deferring and delaying non-COVID–19 care, disruptions in supply chains, fluctuations in facilities' occupancy, absenteeism among staff because of illness or caregiving responsibilities, and increases in mental health concerns.

In the proposed rule, in order to investigate the effects cited by the CDC, we examined the claims data from the FY 2020 MedPAR compared to the FY 2019 MedPAR. Overall, in FY 2020, inpatient admissions under the IPPS dropped by approximately 14 percent compared to FY 2019. Elective surgeries declined significantly, and the share of admissions for MS–DRGs associated with the treatment of COVID–19 increased. For example, the number of inpatient admissions for MS–DRG 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC) dropped by 40 percent in FY 2020. Its share of inpatient admissions dropped from 4.0 percent in FY 2019 to 2.8 percent in FY 2020. The number of inpatient admissions for MS–DRG 177 (Respiratory Infections and Inflammations with MCC) increased by +133 percent. Its share of inpatient admissions increased from 0.8 percent in FY 2019 to 2.2 percent in FY 2020. This data analysis from the proposed rule was consistent with the observations in the CDC's guidance that COVID–19 increased the number of patients seeking care for respiratory illnesses, and caused patients to defer and delay non-COVID–19 care. In the proposed rule, we noted that these observed changes in the claims data also extend to the cost reports submitted by hospitals that include the COVID–19 PHE time period, since those cost reports that extend into the COVID–19 PHE are based in part on the discharges that occurred during that time.

In the proposed rule, we concluded that the effects noted by the CDC are specific to the pandemic and to the extent that the effects on healthcare facilities noted by the CDC are not expected to continue into FY 2022, it would suggest that the inpatient data from FY 2020 impacted by the COVID–19 PHE may be less suitable for use in the FY 2022 ratesetting.

In the proposed rule, we also considered the analysis of 2020 IPPS real case-mix included in the notice titled ''CY 2021 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts'' that appeared in the **Federal Register** on November 12, 2020 (85 FR 71916). Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by the best estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates to hospitals, and adjusted to reflect changes in real case-mix.

To develop the adjustment to reflect changes in real case-mix, we first calculated an average case-mix for each hospital that reflected the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the IPPS in FY 2020 compared to FY 2019, using Medicare claims from IPPS hospitals received as of July 2020. Those claims represented a total of about 6.1 million Medicare discharges for FY 2020 and provided the most recent case-mix data available at the time of that analysis. Based on these claims, the change in average case-mix in FY 2020 was 2.8 percent. Based on these claims and past experience, we expected the overall case-mix change to be 3.8 percent as the year progressed and more FY 2020 data became available.

Real case-mix is that portion of case-mix that is due to changes in the mix of cases in the hospital and not due to coding optimization. As stated in the November 2020 notice, COVID–19 has complicated the determination of real case-mix increase. COVID–19 cases typically group to higher-weighted MS–DRGs, and hospitals have experienced a concurrent reduction in cases that group to lower weighted MS–DRGs. Both of these factors cause a real increase in case-mix. We compared the average case-mix for February 2020 through July 2020 (COVID–19 period) with average case-mix for October 2019 through January 2020 (pre-COVID–19 period). Since this increase applies for only a portion of CY 2020, we allocated this increase by the estimated discharges over the 2 periods—a 2.5 percent increase for FY 2020. The 1.3-percent residual case-mix increase is a mixture of real case-mix and coding optimization. Over the past several years, we have observed total case-mix increases of about 0.5 percent per year and have assumed that they are real. Thus, based on the information available, we expect that 0.5 percent of the residual 1.3 percent change in average case-mix for FY 2020 will be real. The combination of the 2.5 percent COVID–19 effect and the remaining residual 0.5-percent real case-mix increase results in an estimated 3.0 percent increase in real case-mix for FY 2020.

Because this analysis was based on Medicare claims from IPPS hospitals received as of July 2020, in the proposed rule, we calculated case-mix values for FY 2019 and FY 2020 based on the full year FY 2019 and FY 2020 MedPAR files to help assess the change in case-mix based on more complete data. For FY 2019 we calculated a case-mix value of 1.813 and for FY 2020 we calculated a case-mix value of 1.883, an increase in total case-mix of 3.9 percent. These were calculated using the MS–DRG relative weights in effect for those time periods.[5] This was consistent with the estimate in the Notice of the CY 2021 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts that the change in total case-mix for FY 2020 would be 3.8 percent when more complete data was available.

The increases in patients seeking care for respiratory illnesses and patients deferring and delaying non-COVID–19 care during FY 2020, the increasing number of vaccinations for COVID–19, and the high estimate of FY 2020 real case-mix growth all led us to believe that FY 2020 is not the best overall approximation of inpatient experience in FY 2022 and that FY 2019 as the most recent complete FY prior to the COVID–19 PHE is a better approximation of FY 2022 inpatient experience.

As we indicated in the proposed rule, whether the data is a better overall

[5] Section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act directs the Secretary of HHS to increase the weighting factor of the assigned DRG by 20 percent for an individual diagnosed with COVID–19 discharged during the COVID–19 PHE period. In order to make the case-mix values more comparable, the 20 percent increase is not included.

approximation of FY 2022 inpatient experience is one factor in assessing which data source represents the best available data for the FY 2022 rulemaking. Another factor is to what extent the decision to use the FY 2019 or FY 2020 data differentially impacts the FY 2022 ratesetting. One way to assess this factor is to model the change in the total case-mix, which is a driver of spending, if our assumption regarding the FY 2022 inpatient experience used in calculating the MS–DRG relative weights turns out to be less accurate based on actual FY 2022 experience. In the proposed rule, we estimated the difference in the total case-mix if we calculated the MS–DRG relative weights based on the FY 2019 claims data and the actual utilization is ultimately more similar to the FY 2020 data, as compared to if we calculated the MS–DRG relative weights based on the FY 2020 data and the actual utilization is ultimately more similar to the FY 2019 data.

We first calculated a set of MS–DRG relative weights using an assumption that the FY 2022 inpatient experience would be similar to the FY 2019 data. Specifically, we used the proposed version 39 GROUPER (which would be applicable to discharges occurring in FY 2022) and the FY 2019 MedPAR data to calculate MS–DRG relative weights. We refer to these MS–DRG relative weights as the FY 2019-based weights.

We next calculated a set of MS–DRG relative weights using an assumption that the FY 2022 inpatient experience would be more similar to the FY 2020 data. Specifically, we used the proposed version 39 GROUPER and the FY 2020 MedPAR data to calculate MS–DRG relative weights. This is how we would ordinarily calculate the proposed FY 2022 MS–DRG relative weights. We refer to these MS–DRG relative weights as the FY 2020-based weights.

We then estimated the difference in case-mix under the FY 2019-based weights and the FY 2020-based weights if the FY 2022 inpatient experience ended up being the reverse of the assumption made when calculating that set of relative weights. In other words, we compared estimated case-mix calculated under four different scenarios. For the FY 2019-based weights, we calculated the case-mix using claims from the FY 2019 MedPAR as an approximation of the actual FY 2022 experience (Scenario A), and using claims from the FY 2020 MedPAR as an approximation of the actual FY 2022 experience (Scenario B). For the FY 2020-based weights, we calculated the case-mix using claims from the FY 2020 MedPAR as an approximation of the actual FY 2022 experience (Scenario C), and using claims from the FY 2019 MedPAR as an approximation of the actual FY 2022 experience (Scenario D).

The results are shown in the following table.

Scenario	Assumed FY 2022 Experience for Relative Weights	Actual FY 2022 Experience	Case-mix	Assumption Matched Experience?	Percent Change in Case-mix if Mismatch between Assumption and Actual Experience
A	FY 2019	FY 2019	1.820	Yes	
B	FY 2019	FY 2020	1.885	No	0.0%
C	FY 2020	FY 2020	1.885	Yes	
D	FY 2020	FY 2019	1.816	No	-0.2%

In Scenario A and Scenario C, there is by definition no differential impact on total case-mix due to a less accurate assumption made when the MS–DRG relative weights were calculated: The FY 2022 inpatient experience matches the assumption used when the MS–DRG relative weights were calculated. In Scenario B and Scenario D, it is the reverse of the assumption used when the MS–DRG relative weights were calculated.

In the proposed rule, we explained that in Scenario B, when the FY 2019-based weights were used, but the FY 2022 inpatient experience turns out to be more similar to FY 2020 data, the less accurate assumption does not differentially impact the modelled case-mix. This can be seen by comparing the modelled case-mix under Scenario B (1.885) with the modelled case-mix under Scenario C (also 1.885). In other words, if the FY 2019-based weights and inpatient experience turn out to be more similar to the FY 2020 data, then the modelled case-mix is approximately the same as if we had used the FY 2020-based weights. The results show that use of the FY 2019-based weights did not impact the modelled case-mix compared to using the FY 2020-based weights.

In the proposed rule, we explained that the same conclusion is not true of Scenario D where the FY 2020-based weights were used, but the FY 2022 inpatient experience turns out to be more similar to FY 2019 data. Here the less accurate assumption does differentially impact the modelled case-mix, by −0.2 percent. This can be seen by comparing the modelled case-mix under Scenario D (1.816) with the modelled case-mix under Scenario A (1.820). In other words, if we use the FY 2020-based weights, and FY 2022 inpatient experience turns out to be more similar to FY 2019 data, the modelled case-mix is −0.2 percent lower than if we had used the FY 2019-based weights. This shows that use of the FY 2020-based weights does impact the modelled case-mix compared to a result from using the FY 2019-based weights.

Putting aside that we believe FY 2019 is a more likely approximation of the FY 2022 inpatient experience for the reasons discussed earlier, the previous analysis from the proposed rule indicates that the differential effect of the FY 2022 MS–DRG relative weights is more limited if the FY 2019-based weights are used than it is if the FY 2020-based weights are used, should the FY 2022 inpatient experience not match the assumption used to calculate the MS–DRG relative weights.

Another payment factor that is impacted by the use of the FY 2019 or FY 2020 data in the FY 2022 ratesetting is the outlier fixed-loss threshold. As discussed in section II.A.4.j. of the proposed rule, section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of certain payments and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments. We target 5.1 percent within this range. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. In other words, outlier payments are prospectively estimated to be budget neutral overall under the IPPS.[6]

In the proposed rule, under an assumption that the FY 2022 inpatient experience will be more similar to FY 2019 data, we estimated an outlier fixed-loss amount of $30,967. Under an assumption that FY 2022 inpatient experience will be more similar to FY 2020 data, we estimated an outlier fixed-loss amount of $36,843, a difference of $5,876 or approximately 20 percent higher. Again, putting aside that we believe FY 2019 is a better approximation of the FY 2022 inpatient experience for the reasons discussed earlier, we concluded in the proposed rule that the difference between the two estimated outlier fixed-loss amounts means there is a consequence to making a decision as to the best available data for estimating the FY 2022 outlier fixed-loss amount in the form of potentially exceeding or falling short of the targeted 5.1 percent of total operating DRG payments plus outlier payments.

In summary, in the proposed rule, we highlighted two factors in the decision regarding the best available data to use in the FY 2022 ratesetting. The first factor was to what extent the FY 2019 data from before the COVID–19 PHE is a better overall approximation of FY 2022 inpatient experience, or alternatively, to what extent the FY 2020 data including the COVID–19 PHE time period is a better overall approximation of FY 2022 inpatient experience. After analyzing this issue and for the reasons discussed, in the proposed rule we stated our belief that FY 2019 is generally a better overall approximation of FY 2022. The second factor was to what extent the decision to use the FY 2019 or FY 2020 data differentially impacts the FY 2022 IPPS ratesetting. After analyzing this issue, in the proposed rule we determined that the decision does differentially impact the overall FY 2022 IPPS ratesetting in two primary ways. First, a decision to base the MS–DRG relative weights on the FY 2020 data has an impact of −0.2 percent if the FY 2022 inpatient experience is more like FY 2019 data. Second, the decision to use the FY 2019 or FY 2020 data results in an approximately 20 percent difference in the estimate of the outlier fixed-loss amount.

Taking these factors into account, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25089) we proposed to use the FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE, primarily in that the data reflect generally markedly different utilization for certain types of services in FY 2020 than would have been expected in the absence of the PHE, as discussed previously. For example, we proposed to use the FY 2019 MedPAR claims data for purposes where we ordinarily would have used the FY 2020 MedPAR claims data, such as in our analysis of changes to MS–DRG classifications (as discussed in greater detail in section II.D. of the preamble of the proposed rule). Similarly, we proposed to use cost report data from the FY 2018 HCRIS file for purposes where we ordinarily would have used the FY 2019 HCRIS file, such as in determining the FY 2022 IPPS MS–DRG relative weights (as discussed in greater detail in section II.E. of the preamble of the proposed rule). (As noted previously, the FY 2019 HCRIS data would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period.)

In section I.O. of Appendix A of the proposed rule, we stated that we were considering, as an alternative to this proposal, the use of the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting, and which we may consider finalizing based on consideration of comments received. To facilitate comment on this alternative for FY 2022, we made data and other supplemental files available. We refer the reader to section I.O. of Appendix A of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25784) for more information on these supplemental files and where they may be found.

Comment: The vast majority of commenters were fully supportive of our proposal to use the FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE. A commenter was supportive of our proposal but noted that transplant volume was higher in 2020 than 2019. However, the commenter stated that it recognized that due to the nature of hospital admissions during 2020 and the number and types of procedures provided in the hospital during the PHE, use of 2019 data is necessary.

A commenter who stated they did not disagree with our proposal, expressed a concern that surges in COVID–19 cases could still occur in the future, making it impossible to predict what FY 2022 will look like. The commenter mentioned the slowing COVID–19 vaccination rate in many areas and the emergence of new COVID–19 variants that the COVID–19 vaccines were not tested against as reasons to support this concern.

Some commenters were supportive of our proposal, but urged CMS to make or consider certain technical adjustments when calculating the FY 2022 relative weights. We refer readers to section II.E. of the preamble to this final rule for a complete discussion of these comments. A few commenters objected to CMS not using FY 2020 data to calculate the payment adjustment for CAR T-cell clinical trial and expanded access use immunotherapy cases. We refer readers to section V.M. of the preamble to this final rule for a complete discussion of these comments. A commenter expressed concern about not using FY 2020 data in FY 2022 ratesetting for the LTCH PPS, in particular with respect to how the additional costs LTCHs incurred in 2020 will be reflected in future years' rates. We believe this commenter may have misunderstood the role of the market basket update and refer readers to section VIII.A.4. of the preamble to this final rule for a complete discussion of this comment.

Response: We appreciate the commenters' support of our proposal to use the FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE. In response to the commenter who expressed concerns about the possibility of future surges in COVID–19 making it impossible to predict what FY 2022 will look like, we appreciate the feedback. However, we believe the most recent vaccination and

[6] More information on outlier payments may be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-forService-Payment/AcuteInpatientPPS/outlier.html.*

hospitalization data reported by the CDC, discussed later in this section, support our assumption that there will be significantly lower risk of COVID–19 in FY 2022 and fewer hospitalizations for COVID–19 for Medicare beneficiaries in FY 2022 than there were in FY 2020. To address to the extent possible the commenter's concerns about the efficacy of the COVID–19 vaccines against new variants, we refer the reader to the June 25th weekly summary report from the CDC that states ''recent studies have shown that the vaccines available in the United States are effective against variants currently circulating, including B.1.617.2.'' [7]

Since the publication of the proposed rule, we have continued to monitor the vaccination and hospitalization data reported by the CDC (see *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07022021.html*, accessed July 6, 2021). As of July 1, 2021, 328.2 million vaccine doses have been administered. Overall, about 181.3 million people, or 54.6 percent of the U.S. population, have received at least one dose of vaccine as of this date. About 155.9 million people, or 47.0 percent of the U.S. population have been fully vaccinated. As of July 1, the 7-day average number of administered vaccine doses reported to CDC per day was 334,816, a 45.3 percent decrease from the previous week. As of July 1, 2021, 88.2 percent of people 65 or older have received at least one dose of vaccine; 78.3 percent are fully vaccinated. Two-thirds (66.7 percent) of people 18 or older have received at least one dose of vaccine; 57.7 percent are fully vaccinated. Nationally, the COVID–19-related 7-day moving average for new hospital admissions has been generally decreasing since publication of the proposed rule, demonstrating the important role vaccination is playing in protecting against COVID–19. As of July 3, 2021 (the most recent date with data available at the time of writing), the 7-day moving average for new hospital admissions was 1,821, down significantly from the 7-day moving average peak of 16,492 recorded on January 9th, 2021 and the 7-day moving average of 5,075 recorded on April 27, 2021, the date the proposed rule was issued.[8]

In the proposed rule, we analyzed the significant growth in real-case mix observed in the FY 2020 MedPAR claims data. This analysis was consistent with the observations in the CDC's guidance that COVID–19 increased the number of patients seeking care for respiratory illnesses, and caused patients to defer and delay non-COVID–19 care. While we acknowledge that the rate of vaccination for the U.S. population has slowed considerably since we released the proposed rule, the total number of vaccines administered, especially for people 65 or older, along with the latest hospitalization trends, lead us to continue to believe that there will be a significantly lower risk of COVID–19 in FY 2022 and fewer hospitalizations for COVID–19 for Medicare beneficiaries in FY 2022 than there were in FY 2020. For these reasons, we continue to believe that FY 2020 is not the best overall approximation of inpatient experience in FY 2022 and that FY 2019 as the most recent complete FY prior to the COVID–19 PHE is a better approximation of FY 2022 inpatient experience.

Therefore, after considering the comments received and evaluating the most recent vaccination and hospitalization data from the CDC, we are finalizing our proposal to use the FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE, primarily in that the data reflect generally markedly different utilization for certain types of services in FY 2020 than would have been expected in the absence of the PHE, as discussed previously. For example, in this final rule we used the FY 2019 MedPAR claims data for purposes where we ordinarily would have used the FY 2020 MedPAR claims data, such as in our analysis of changes to MS–DRG classifications (as discussed in greater detail in section II.D. of the preamble of this final rule). Similarly, we used cost report data from the FY 2018 HCRIS file for purposes where we ordinarily would have used the FY 2019 HCRIS file, such as in determining the FY 2022 IPPS MS–DRG relative weights (as discussed in greater detail in section II.E. of the preamble of this final rule). (As noted previously, the FY 2019 HCRIS data would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period.)

We note that MedPAR claims data and cost report data from the HCRIS file are examples of the data sources for which we discuss the use of the FY 2019 data for the FY 2022 ratesetting in this final rule. We have clearly identified throughout this final rule where and how we are using alternative data than what ordinarily would be used for the FY 2022 IPPS and LTCH PPS ratesetting, including certain provider specific information.

II. Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2021 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085, 83 FR 41158 through 41258, 84 FR 42058 through 42165, and 85 FR 58445 through 58596 respectively).

[7] Keep Variants at Bay. Get Vaccinated Today., available at *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/06252021.html* accessed July 6, 2021).

[8] New Admissions of Patients with Confirmed COVID–19., available at *https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions* accessed July 3, 2021).

C. FY 2022 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90 and the Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA).

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percentage points to the national standardized amount. We provided for phasing in this −4.8 percentage point adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percentage points for FY 2008, −1.8 percentage points for FY 2009, and −1.8 percentage points for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percentage point for FY 2008 and −0.9 percentage point for FY 2009.

As discussed in prior year rulemakings, and most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56780 through 56782), we implemented a series of adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90, based on a retrospective review of FY 2008 and FY 2009 claims data. We completed these adjustments in FY 2013 but indicated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53275) that delaying full implementation of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated, and that these overpayments could not be recovered under Public Law 110–90. In addition, as discussed in prior rulemakings and most recently in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38008 through 38009), section 631 of the American Taxpayer Relief Act of 2012 (ATRA) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

2. Adjustments Made for FYs 2018, 2019, 2020, and 2021 as Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. Section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted on December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from a 0.5 percentage point positive adjustment to a 0.4588 percentage point positive adjustment. As we discussed in the FY 2018 rulemaking, we believe the directive under section 15005 of Public Law 114–255 is clear. Therefore, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38009) for FY 2018, we implemented the required +0.4588 percentage point adjustment to the standardized amount. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41157), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42057), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58444 and 58445), consistent with the requirements of section 414 of the MACRA, we implemented 0.5 percentage point positive adjustments to the standardized amount for FY 2019, FY 2020, and FY 2021, respectively. We indicated the FY 2018, FY 2019, FY 2020, and FY 2021 adjustments were permanent adjustments to payment rates. We also stated that we plan to propose future adjustments required under section 414 of the MACRA for FYs 2022 and 2023 in future rulemaking.

3. Adjustment for FY 2022

Consistent with the requirements of section 414 of the MACRA, we proposed to implement a 0.5 percentage point positive adjustment to the standardized amount for FY 2022. We stated that this proposed adjustment would constitute a permanent adjustment to payment rates. We also stated that we plan to propose the final adjustment required under section 414 of the MACRA for FY 2023 in future rulemaking.

Comment: A commenter reiterated their position from prior year comments that CMS misinterpreted the relevant statutory authority, which they believe explicitly assumes that the ATRA recoupment would result in negative adjustments totaling −3.2 percentage points completed through FY 2017, rather than the cumulative −3.9 percentage point adjustment made by CMS. The commenter stated that CMS should have made an additional 0.7 percent positive adjustment to the standardized amount in FY 2018. The commenter stated that the failure to make this adjustment resulted in an incorrect reduction in the standardized amount for all subsequent years. We also received multiple comments recommending that CMS commit to use its authority (a commenter specifically citing CMS's authority under § 1886(d)(5)(I) of the Act) to restore the full amount of the cumulative −3.9 percentage point adjustment made to achieve the $11 billion targeted by the ATRA. A commenter requested CMS

specify the method for full repayment of this reduction to all providers by FY 2023 in the final rule, instead of waiting until future rulemaking to propose the final adjustment for FY 2023.

Response: As we discussed in response to a similar comment in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58444 through 58445) and in prior rules, we believe section 414 of the MACRA and section 15005 of the 21st Century Cures Act set forth the levels of positive adjustments for FYs 2018 through 2023. We are not convinced that the adjustments prescribed by MACRA were predicated on a specific adjustment level estimated or implemented by CMS in previous rulemaking. We see no evidence that Congress enacted these adjustments with the intent that CMS would make an additional +0.7 percentage point adjustment in FY 2018 to compensate for the higher than expected final ATRA adjustment made in FY 2017, nor are we persuaded that it would be appropriate to use the Secretary's exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to adjust payments in FY 2022 to restore any additional amount of the original 3.9 percentage point reduction, given Congress' prescriptive adjustment levels under section 414 of the MACRA and section 15005 of the 21st Century Cures Act. CMS did not propose the specific level of adjustment to be made in FY 2023, and therefore we will proceed as planned to discuss the future (and final) adjustment under section 414 of the MACRA in FY 2023 rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to implement a 0.5 percentage point adjustment to the standardized amount for FY 2022.

D. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for FY 2022 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for FY 2022 MS–DRG Updates

Given the need for more time to carefully evaluate requests and propose updates, as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38010), we changed the deadline to request updates to the MS–DRGs to November 1 of each year, which provided an additional five weeks for the data analysis and review process. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32472), we stated that with the continued increase in the number and complexity of the requested changes to the MS–DRG classifications since the adoption of ICD–10 MS–DRGs, and in order to consider as many requests as possible, more time is needed to carefully evaluate the requested changes, analyze claims data, and consider any proposed updates. We further stated we were changing the deadline to request changes to the MS–DRGs to October 20 of each year to allow for additional time for the review and consideration of any proposed updates. However, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58445), due to the unique circumstances for the FY 2021 IPPS/LTCH PPS final rule for which we waived the delayed effective date, we maintained the deadline of November 1, 2020 for FY 2022 MS–DRG classification change requests. We also noted that we expected to reconsider a change in the deadline beginning with comments and suggestions submitted for FY 2023. We stated in the proposed rule that while we continue to believe that a change in the deadline from November 1 to October 20 will provide hospitals sufficient time to assess potential impacts and inform future MS–DRG recommendations, we are maintaining the deadline of November 1 for FY 2023 MS–DRG classification change requests.

Comment: Commenters expressed support for a future change to the deadline for requesting updates to the MS–DRG classifications from November 1 to October 20. The commenters also recommended that CMS consider implementing an additional submission deadline, such as earlier in the calendar year. According to the commenters, while the current process to submit requests for changes to the MS–DRG classifications may be submitted at any time prior to the fall deadline, a second target submission date may encourage interested parties to submit requests earlier in the year and enable additional time for CMS to carefully evaluate requested changes, analyze claims data and consider proposed changes.

Response: We appreciate the commenters feedback and support for our discussion regarding a future change to the deadline for requesting updates to the MS–DRG classifications from November 1 to October 20. We also thank the commenters for the suggestion to add a second submission date, and may consider any changes to the deadline and/or the frequency for submissions of requests for MS–DRG classification changes for future fiscal years.

Interested parties had to submit MS–DRG classification change requests for FY 2022 by November 1, 2020, and the comments that were submitted in a timely manner for FY 2022 are discussed in this section of the preamble of this final rule. As we discuss in the sections that follow, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking. Interested parties should continue to submit any comments and suggestions for FY 2023 by November 1, 2021 via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov*.

We provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 39, in connection with the FY 2022 IPPS/LTCH PPS proposed rule so that the public could better analyze and understand the impact of the proposals included in the proposed rule. We noted that this test software reflected the proposed GROUPER logic for FY 2022. Therefore, it included the new diagnosis and procedure codes that are effective for FY 2022 as reflected in Table 6A.—New Diagnosis Codes—FY 2022 and Table 6B.—New Procedure Codes—FY 2022 that were associated with the proposed rule and did not include the diagnosis codes that are invalid beginning in FY 2022 as reflected in Table 6C.—Invalid Diagnosis Codes—

FY 2022 and Table 6D.—Invalid Procedure Codes—FY 2022 that was associated with the proposed rule. Those tables were not published in the Addendum to the proposed rule, but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to the proposed rule. Because the diagnosis and procedure codes no longer valid for FY 2022 are not reflected in the test software, we made available a supplemental file in Table 6P.1a that included the mapped Version 39 FY 2022 ICD–10–CM codes and the deleted Version 38 FY 2021 ICD–10–CM codes that should be used for testing purposes with users' available claims data. In addition, we made available a supplemental file in Table 6P.1b that included the mapped Version 39 FY 2022 ICD–10–PCS codes and the deleted Version 38 FY 2021 ICD–10–PCS codes that should be used for testing purposes with users' available claims data. Therefore, users had access to the test software allowing them to build case examples that reflect the proposals that were included in the proposed rule. In addition, users were able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 39.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 39, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 39, and the supplemental mapping files in Table 6P.1a and Table 6P.1b of the FY 2021 and FY 2022 ICD–10–CM diagnosis and ICD–10–PCS procedure codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

Following are the changes that we proposed to the MS–DRGs for FY 2022. We invited public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in the proposed rule. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. In other cases, we proposed to maintain the existing MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. As discussed in section I.F of the preamble of the proposed rule, we proposed to use claims data from the March 2020 update of the FY 2019 MedPAR file in our analysis of proposed MS–DRG classification changes for FY 2022, consistent with our goal of using the best available data overall for ratesetting. Alternatively, we also provided the results of our analysis of proposed MS–DRG classification changes using claims data from the September 2020 update of the FY 2020 MedPAR file. As a result, for the FY 2022 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the March 2020 update of the FY 2019 MedPAR file, which contains hospital claims received from October 1, 2018 through March 31, 2020, for discharges occurring through September 30, 2019. In addition, we also analyzed ICD–10 claims data from the September 2020 update of the FY 2020 MedPAR file, which contains hospital claims received from October 1, 2019 through September 30, 2020, for discharges occurring through September 30, 2020. In our discussion of the proposed MS–DRG reclassification changes, we referred to these claims data as the ''March 2020 update of the FY 2019 MedPAR file'' and ''the September 2020 update of the FY 2020 MedPAR file.''

In this FY 2022 IPPS/LTCH PPS final rule, we summarize the public comments we received on our proposals, present our responses, and state our final policies. For this FY 2022 final rule, we generally did not perform any further MS–DRG analysis of claims data. Therefore, the MS–DRG analysis is based on ICD–10 claims data from both the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, as set forth in the proposed rule, except as otherwise noted. As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. We stated we believed that applying these criteria to the NonCC subgroup would better reflect resource stratification as well as promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We noted that in our analysis of MS–DRG classification requests for FY 2021 that were received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups. We also noted that the application of the NonCC subgroup criteria going forward may result in modifications to certain MS–DRGs that are currently split into three severity levels and result in MS–DRGs that are split into two severity levels. We stated that any proposed modifications to the MS–DRGs would be addressed in future rulemaking consistent with our annual process and reflected in Table 5—Proposed List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for the applicable fiscal year.

In our analysis of the MS–DRG classification requests for FY 2022 that we received by November 1, 2020, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we typically evaluate the most recent year of MedPAR claims data available. For example, in the FY 2022 IPPS/LTCH PPS proposed rule we stated our MS–DRG analysis was based on ICD–10 claims data from both the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we typically analyze the most recent two years of data. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria is satisfied for a three way split. If the criteria fail, the next step is to determine if the criteria are satisfied for a two way split. If the criteria for both of the two way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS–DRG. If the three way split fails on any one of the five criteria and all five criteria for both two way splits (1_23 and 12_3) are met, we would apply the two way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS–DRG into severity levels specifies the request is for either one of the two way splits (1_23 or 12_3), in response to the specific request, we will evaluate the criteria for both of the two way splits, however we do not also evaluate the criteria for a three way split.

In the FY 2022 IPPS/LTCH PPS proposed rule, we stated that using the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, we analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2022. We noted that findings from our analysis indicated that approximately 32 MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. Specifically, we found that applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would result in the deletion of 96 MS–DRGs (32 MS–DRGs × 3 severity levels = 96) and the creation of 58 new MS–DRGs. We further noted that these updates would also involve a redistribution of cases, which would impact the relative weights, and, thus, the payment rates proposed for particular types of cases. We referred the reader to Table 6P.1c associated with the proposed rule for the list of the 96 MS–DRGs that would be subject to deletion and the list of the 58 new MS–DRGs that would be proposed for creation for FY 2022 under this policy if the NonCC subgroup criteria were applied.

We stated in the proposed rule that in light of the public health emergency (PHE), we had concerns about the impact of implementing this volume of MS–DRG changes at this time, and our belief that it may be appropriate to delay application of the NonCC subgroup criteria to existing MS–DRGs in order to maintain more stability in the current MS–DRG structure. Therefore, we proposed to delay the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split until FY 2023, and proposed for FY 2022 to maintain the current structure of the 32 MS–DRGs that currently have a three-way severity level split (total of 96 MS–DRGs) that would otherwise be subject to these criteria.

Comment: Several commenters expressed support for our proposal to delay the application of the expanded three-way severity level split criteria to the NonCC subgroup until fiscal year 2023 in light of the PHE, and to maintain the current structure of the MS–DRGs. Many commenters also recommended that a complete analysis of the MS–DRG changes to be proposed for fiscal year 2023 in connection with the expanded three-way severity split criteria be conducted and made available to enable the public an opportunity to review and consider the redistribution of cases, the impact to the relative weights (for example, Table 5—Proposed List of Medicare Severity

Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay), payment rates and hospital case mix to allow meaningful comment prior to implementation. A few commenters suggested delaying the application of the expanded three-way severity split NonCC subgroup criteria until fiscal year 2024 to allow analysis of claims data from FY 2022 that may better reflect post pandemic utilization. Another commenter recommended delaying any changes until FY 2025.

A commenter expressed concern that changes to the underlying MS–DRG structure may inadvertently exacerbate payment differentials between different types of hospitals (e.g., urban versus rural) based on the types of services they provide, which may negatively impact Medicare beneficiary access to some services. Another commenter stated it reviewed its hospital specific data and had concerns that the ''with cc'' level will be reduced on several MS–DRGs. This commenter stated that if its case mix remains the same it would continue to treat many patients with comorbid conditions and receive payment consistent with a MS–DRG at the ''without CC'' level. The commenter identified the following four MS–DRGs that appeared to be impacted the most with respect to lost revenue, MS–DRG 617 (Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorder with CC); MS–DRG 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC); MS–DRG 854 (Infectious and Parasitic Diseases with O.R. Procedure with CC) and MS–DRG 958 (Other O.R. Procedures for Multiple Significant Trauma with CC). Lastly, the commenter recommended that CMS also further assess other proposed groupings, such as the maternity MS–DRGs, due to historically low volumes in these MS–DRGs and to determine if it would be appropriate to combine any of them.

Another commenter requested that CMS provide data transparency to illustrate volumes by MS–DRG that support the proposal for changes to the 96 MS–DRGs discussed in the FY 2022 IPPS/LTCH PPS proposed rule and to also consider patient mix for the obstetric MS–DRGs. This commenter also suggested that CMS examine the impact for surgical versus medical MS–DRGs with respect to redistribution and associated impacts to the relative weights. According to the commenter, the impact appears to be greater for surgical MS–DRGs.

Finally, a commenter who expressed support for CMS' proposal to delay implementation of the expanded three-way severity split criteria to the NonCC subgroup recommended that any proposed changes to the structure of the MS–DRGs should consist of the impact of the proposed CC/MCC redesign and not the current CC/MCC structure that is scheduled to be changed.

Response: We appreciate the commenters' support. In response to the recommendation that a complete analysis of the MS–DRG changes to be proposed for FY 2023 in connection with the application of the expanded three-way severity split criteria to the NonCC subgroup be conducted and made publicly available, we plan to perform and make publicly available a more detailed analysis in connection with any future proposed changes, consistent with our annual claims analysis for MS–DRG classification change proposals. With respect to the commenters who suggested delaying the application of the expanded three-way severity split NonCC subgroup criteria until fiscal year 2024 or later, including to allow the use of FY 2022 claims data, we appreciate the feedback and will take these suggestions under consideration.

In response to the commenters who expressed concern that changes to the underlying MS–DRG structure may inadvertently exacerbate payment differentials between different types of hospitals based on the types of services they provide, or would have the greatest impacts with respect to particular MS–DRGs, we note that generally, changes to the MS–DRG classifications and related policies under the IPPS that are implemented on an annual basis may affect payment for different types of hospitals depending on the services they provide, and, note that we intend to conduct and make publicly available analysis of the application of the NonCC subgroup criteria in connection with any future proposed changes, consistent with our annual MS–DRG analysis, including with respect to particular MS–DRGs.

We appreciate the commenters' feedback suggesting further review of the maternity (obstetric) MS–DRGs and agree that these groupings warrant special consideration. As discussed in prior rulemaking (83 FR 41210), we cannot adopt the same approach to refine the maternity and newborn MS–DRGs because of the extremely low volume of Medicare patients there are in these DRGs.

In response to the commenter who requested that CMS provide data transparency to illustrate volumes by MS–DRG that support the proposal for changes to the 96 MS–DRGs discussed in the FY 2022 IPPS/LTCH PPS proposed rule, we refer the reader to Table 6P.1l associated with this final rule and available via the internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. This table displays the volume (case counts) by each MS–DRG based on claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file.

We also thank the commenter for its suggestion to examine the impact for surgical versus medical MS–DRGs and agree that type of information can be useful for stakeholders.

With respect to the commenter who recommended that any proposed changes to the structure of the MS–DRGs should consist of the impact of the proposed CC/MCC redesign and not the current CC/MCC structure that is scheduled to be changed, it is not clear to us from the limited comment if the commenter is referring to the potential changes in connection with the comprehensive CC/MCC analysis that is currently in progress. We note that any proposed modifications to the MS–DRGs would be addressed in future rulemaking, including any proposed changes to the severity level designation of diagnosis codes, and would be considered and taken into account with application of the NonCC subgroup criteria.

After consideration of the public comments we received, we are finalizing our proposal to delay the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split until FY 2023 or later, and are finalizing for FY 2022 to maintain the current structure of the 32 MS–DRGs that currently have a three-way severity level split.

We are making the FY 2022 ICD–10 MS–DRG GROUPER and Medicare Code Editor (MCE) Software Version 39, the ICD–10 MS–DRG Definitions Manual files Version 39 and the Definitions of Medicare Code Edits Manual Version 39 available to the public on our CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

2. Pre-MDC: MS–DRG 018 Chimeric Antigen Receptor (CAR) T-Cell Therapy

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58451 through 58453), we finalized our proposal to create Pre-MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) and to reassign cases reporting ICD–10–PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell

immunotherapy into peripheral vein, percutaneous approach, new technology group 3) or XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3) from Pre-MDC MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy), to new Pre-MDC MS–DRG 018 effective with discharges on and after October 1, 2020. We also finalized our proposal to revise the title for MS–DRG 016 from ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy'' to ''Autologous Bone Marrow Transplant with CC/MCC'' to reflect these changes.

Additionally, in the FY 2021 IPPS/LTCH PPS final rule in response to public comments expressing concern that Pre-MDC MS–DRG 018 is specific to one mechanistic approach to cellular therapy, and in response to commenters who sought clarification on how future CAR T-cell and non-CAR T-cell therapy products would be assigned, we stated that if additional cellular therapies should become available, we would use our established process to determine the MS–DRG assignment. The commenters requested that CMS provide flexibility for future cellular therapies, as they are made available and not restrict Pre-MDC MS–DRG 018 to CAR T-cell therapies alone. In this section of this rule, we discuss the assignment of these therapies in more detail.

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25094), during the September 8–9, 2020 ICD–10 Coordination and Maintenance Committee meeting, several topics involving requests for new procedure codes related to CAR T-cell therapies, non-CAR T-cell therapies and other immunotherapies were discussed. We referred the reader to the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional detailed information regarding these requests for new procedure codes.

As noted in prior rulemaking (85 FR 32543), for new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. As discussed in section II.D.13 of the preamble of the proposed rule and this final rule, Table 6B.—New Procedure Codes, lists the new procedure codes that have been approved to date that will be effective with discharges on and after October 1, 2021. Included in Table 6B are the following new procedure codes that describe the administration of CAR T-cell and non-CAR T-cell therapies and other immunotherapies. As stated in the proposed rule, consistent with our established process, we examined the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment and, consistent with the assignment of those predecessor codes, we proposed to classify the following new procedure codes as non-O.R. procedures affecting Pre-MDC MS–DRG 018, as shown in Table 6B.—New Procedure Codes associated with the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/*.

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ICD-10-PCS Code	Description
XW033C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033H7	Introduction of axicabtagene ciloleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033J7	Introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033K7	Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033L7	Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033M7	Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033N7	Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW043C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7
XW043G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7
XW043H7	Introduction of axicabtagene ciloleucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043J7	Introduction of tisagenlecleucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043K7	Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043L7	Introduction of lifileucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043M7	Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043N7	Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7

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In connection with our proposed assignment of the listed procedure codes to Pre-MDC MS–DRG 018, we also proposed to revise the title for Pre-MDC MS–DRG 018 ''Chimeric Antigen Receptor (CAR) T-cell Immunotherapy'' to ''Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies'' to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies that would also be assigned to this MS–DRG (for example, Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7), in addition to CAR T-cell therapies.

Comment: Several commenters agreed with the proposal to assign the listed ICD–10–PCS procedure codes to Pre-MDC MS–DRG 018 and to revise the title to include ''Other Immunotherapies.'' A commenter who expressed support for the change to Pre-MDC MS–DRG 018 stated its view that the domain of cellular therapeutics will become increasingly important in the care of Medicare beneficiaries with cancer in the future and that creating sufficient plasticity in the diagnostic coding system to permit the continued integration of new and innovative therapeutics into the evidence-based care of Medicare beneficiaries is essential. Another commenter stated they appreciated the recognition of the differentiated nature of cancer care, as well as the importance of innovation in

the domain of immune-oncology, which it stated was a necessary part of effective, equitable cancer care delivery to CMS beneficiaries who receive their care at both PPS and PPS-Exempt centers to ensure equitable access. A commenter stated the proposed change to Pre-MDC MS–DRG 018 furthers the goal of securing expedited access for Medicare beneficiaries to innovative therapies. Another commenter stated the proposal responds to stakeholder concerns that currently, Pre-MDC MS–DRG 018 is specific to one mechanistic approach to cellular therapy. This same commenter and other commenters stated the proposal is also responsive to stakeholder requests that CMS provide flexibility for future cellular therapies as they are made available, and not restrict Pre-MDC MS–DRG 018 to CAR T-cell therapies alone.

However, some commenters who expressed appreciation of CMS' recognition of non-CAR T-cell immunotherapy and a need to revise the description for Pre-MDC MS–DRG 018 requested further clarification from CMS on what the ''Other Immunotherapies'' terminology is intended to include. The commenters stated the term ''Other Immunotherapies'' is very general and may lead to confusion since ''immunotherapy'' is a broad term that is applied across several therapeutic areas (for example Diabetes, Rheumatoid Arthritis, Cancer, etc.) to describe treatments that stimulate an immune response within patients. A commenter stated that the National Cancer Institute differentiates immunotherapy for cancer patients into several types (for example, Immune checkpoint inhibitors, T-cell transfer therapy, Monoclonal antibodies, etc.). This commenter stated their belief that CMS is not intending to refer to a broad array of immunotherapy and suggested that more precise language in the descriptor of Pre-MDC MS–DRG 018 may be beneficial. Some commenters recommended that CMS consider using terminology such as ''Immune Effector Cells'' in place of ''Other Immunotherapies'' with respect to the description of the MS–DRG. Other commenters suggested that CMS consider revising the title for Pre-MDC MS–DRG 018 to ''Autologous T-cell Immunotherapies''. Another commenter stated they recognized the intent of the proposed change and commended the effort by CMS to ensure that future cellular and CAR T-cell therapies are rapidly assigned to a MS–DRG to allow for proper payment, however, similar to other commenters, this commenter requested clarification as to whether the proposed revision to the title of Pre-MDC MS–DRG 18 is intended to incorporate solely cellular and CAR T-cell therapies, or whether the goal is to include all cancer immunotherapeutic agents since the term ''immunotherapy'' is broad and future novel cancer immunotherapeutic agents may have different resource utilization.

A commenter acknowledged that CMS is faced with a challenging landscape in incorporating the administration of new gene and cell therapies into the IPPS and recognized that CMS' proposed assignment of procedure codes describing the administration of tumor-infiltrating lymphocyte (TIL) therapies to MS–DRG 018 is to the most similar MS–DRG that covers similar clinical characteristics and comorbidities. However, whether for TIL therapies or other products in the pipeline, the commenter recommended that CMS consider the following factors when determining a permanent payment mechanism:

- Patient diagnosis and product indication (solid vs. blood cancers)
- Cell collection methodologies (tissue biopsy, pheresis, etc.)
- Product administration methodologies
- Patient clinical care regimes and durations
- Product safety and toxicity profiles that impact inpatient care and follow-up

According to the commenter, society experts state there are distinct and important differences in these factors between TIL therapies and CAR T-cell therapies that may support reconsideration of the MS–DRG assignment after a product is approved by the FDA and is used to treat Medicare beneficiaries. The commenter recommended further consideration of the appropriateness and patient access implications, based on these factors, before grouping the two types of therapies together on a long-term basis. This commenter also suggested that if CMS finalized a change to the title of MS–DRG 018 to include TIL therapies upon their initial approval, as proposed, that the title of the MS–DRG more clearly reflect the specialized products assigned to it.

A few commenters urged CMS to finalize the proposal while continuing to work with stakeholders on ways to improve the predictability and stability of hospital payment for these complex, novel cell therapies that provide options for patients who so desperately need them. Other commenters stated that if the proposed revision to the title for Pre-MDC MS–DRG 018 is finalized, that CMS should continue to monitor and assess the appropriateness of therapies assigned to MS–DRG 018, if they continue to be aligned on resource use, and whether additional refinements or MS–DRGs may be warranted in the future. The commenters also suggested that CMS consider and detail a process for creating new Pre-MDC MS–DRGs that reflect utilization and clinical similarity consistent with the current overall IPPS infrastructure while maintaining important resource and clinical differences to maintain relative weight stability.

Other commenters opposed or expressed strong concerns with the proposal to assign the procedure codes describing non-CAR T-cell and other immunotherapies to Pre-MDC MS–DRG 018 and to revise the title of the MS–DRG. These commenters stated that assigning therapies that are clinically distinct from CAR T-cell therapies and may vary in resource use has the potential to distort future rate setting and will disrupt the Agency's measured multi-year approach in establishing a MS–DRG dedicated to CAR T-cell therapy. According to the commenters, expanding the MS–DRG to other immunotherapies one year after it has been implemented holds the risk of creating additional payment uncertainty around CAR T-cell therapies. The commenters urged CMS to maintain Pre-MDC MS–DRG 018 specifically for autologous CAR T-cell therapies only, as a long-term solution for reliable and predictable payments that will enable hospitals to provide access to CAR T-cell therapies for Medicare beneficiaries.

Some commenters recommended that CMS publicly propose MS–DRG mappings in advance of making a final assignment decision and provide an opportunity for stakeholders to submit comments with respect to proposed mappings. Other commenters stated the new technology add-on payment process should be independent of the process for obtaining a MS–DRG assignment for a new code.

A few commenters provided specific information relating to the process that is involved for patients undergoing treatment with CAR T-cell therapy. The commenters outlined the stage of leukapheresis where T-cells are separated and removed from the blood and the remaining blood is returned to the body, followed by the T-cells being sent to a manufacturing facility where they are genetically engineered and grown in a laboratory until millions of T-cells are produced. These commenters did not agree with the assignment of procedure codes describing non-CAR T-cell therapies and other

immunotherapies to Pre-MDC MS–DRG 018 stating the treatment processes are distinctly different and that some products have yet to be approved by the FDA.

A commenter who specifically opposed the modification of Pre-MDC MS–DRG 018 for FY 2022 stated that there are not any non-CAR T-cell therapy FDA approved products that are anticipated in the near term. This commenter further stated that CMS' proposal to include ''other immunotherapies'' in the description for Pre-MDC MS–DRG 018 is overly broad and risks inclusion of therapeutics which are not well aligned with CAR T-cell cases being mapped to this MS–DRG. According to the commenter, CMS has not provided sufficient detail about the rationale and supporting evidence for assignment of non-CAR T-cell products to MS–DRG 018. The commenter also stated that the term ''immunotherapy'' could describe products that treat a range of conditions, and those products may have different experience with potential complications and expected length of stay than CAR T-cell products as well as different costs for the product itself. This same commenter recommended that CMS provide evidence of clinical consistency and resource use alignment in future rulemaking when proposing therapies that may map to Pre-MDC MS–DRG–018 and allow for public comments. Another commenter expressed concern that the proposed change to encompass ''other immunotherapies'' in Pre-MDC MS–DRG 018 could set a precedent for creating ''generic'' MS–DRGs for gene therapies, which, according to the commenter, could hamper timely beneficiary access to needed treatment. This commenter urged CMS to limit Pre-MDC MS–DRG 018 to all types of CAR T-cell therapies and to consider creating new MS–DRGs for therapies, such as gene therapies, outside the CAR T-cell space.

Response: We thank the commenters for their support of our proposal to assign the listed procedure codes describing CAR T-cell, non-CAR T-cell and other immunotherapies to Pre-MDC MS–DRG 018 and to modify the title for Pre-MDC MS–DRG 018 to reflect this assignment. As previously noted, we used our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. Specifically, we reviewed the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we considered other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code. As stated in the preamble of the proposed rule and discussed in this final rule, we proposed to classify the new procedure codes as Non-O.R. procedures affecting Pre-MDC MS–DRG 018, as shown in Table 6B.—New Procedure Codes that was associated with the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/, providing the opportunity for public comment on the MDC, MS–DRG assignment and designation.*

The predecessor code and associated MS–DRG assignment (if applicable) for the listed codes are as follows:

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ICD-10-PCS Code	Description	Predecessor Code	Predecessor MS-DRG
XW033C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	XW033C3 Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3	018
XW033G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	3E033GC Introduction of other therapeutic substance into peripheral vein, percutaneous approach	Non-O.R.
XW033H7	Introduction of axicabtagene ciloleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	XW033C3 Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3	018
XW033J7	Introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	XW033C3 Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3	018
XW033K7	Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	XW033C3 Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3	018
XW033L7	Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	3E033GC Introduction of other therapeutic substance into peripheral vein, percutaneous approach	Non-O.R.
XW033M7	Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	XW23346 Transfusion of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6	018
XW033N7	Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	XW23376 Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6	018

ICD-10-PCS Code	Description	Predecessor Code	Predecessor MS-DRG
XW043C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	XW043C3 Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3	018
XW043G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	3E043GC Introduction of other therapeutic substance into central vein, percutaneous approach	Non-O.R.
XW043H7	Introduction of axicabtagene ciloleucel immunotherapy into central vein, percutaneous approach, new technology group 7	XW043C3 Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3	018
XW043J7	Introduction of tisagenlecleucel immunotherapy into central vein, percutaneous approach, new technology group 7	XW043C3 Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3	018
XW043K7	Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7	XW043C3 Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3	018
XW043L7	Introduction of lifileucel immunotherapy into central vein, percutaneous approach, new technology group 7	3E043GC Introduction of other therapeutic substance into central vein, percutaneous approach	Non-O.R.
XW043M7	Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7	XW24346 Transfusion of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 6	018
XW043N7	Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7	XW24376 Transfusion of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 6	018

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As shown in the table, all the procedure codes have a predecessor code that was previously assigned to Pre-MDC MS–DRG 018 with the

exception of four procedure codes (XW033G7, XW033L7, XW043G7, and XW043L7) that have a predecessor code that was designated Non-O.R. and did not impact any MS–DRG assignment. Two of the four codes describe the introduction (administration) of an allogeneic CAR T-cell therapy and are intended to capture any allogeneic CAR T-cell products that may become available and do not yet have a unique procedure code. The other two codes specifically describe the product lifileucel. We believe that at this time, as the field of cellular and gene immunotherapies is continuing to evolve very rapidly, that it is appropriate to initially classify the procedure codes describing allogeneic CAR T-cell therapy and lifileucel to Pre-MDC MS–DRG 018 because there are clinical similarities with respect to the administration of these products, the complexity of the conditions in which they are treating, and resource utilization that are consistent with other CAR T-cell products currently assigned to the MS–DRG. As a commenter specifically noted in its support to assign the procedure codes describing the introduction of lifileucel (XW033L7 and XW043L7) to Pre-MDC MS–DRG 018, both lifileucel (a tumor-infiltrating lymphocyte or TIL therapy) and CAR T-cell therapies require collection of a patient's lymphocyte cells which are a key component of a complicated manufacturing process to produce a patient-specific therapeutic dose, both are primarily administered in the inpatient setting due to risk of significant but treatable adverse events and the resources are anticipated to be comparable with respect to the intensity of patient care that includes the treatment phase, monitoring, management of any adverse events, and length of stay. While for TIL therapy the source of the lymphocyte is the patient's tumor and is obtained through surgical resection, and for CAR T-cell therapy the source of the lymphocyte is the patient's blood, obtained through apheresis, both therapies require a patient's lymphocytes. We also appreciate another commenter's recognition of the challenges involved with incorporating the administration of new gene and cellular therapies into the IPPS and the view that assignment of procedure codes describing the administration of tumor-infiltrating lymphocyte (TIL) therapies to Pre-MDC MS–DRG 018 is to the most similar MS–DRG that reflects similar clinical characteristics and comorbidities. With respect to allogeneic CAR T-cell therapies, it is understood that these therapies are not derived from a patient's own cells and therefore are not ''autologous'', however, the resources and complexity in the care and clinical management of these patients may be considered comparable when taking into account diagnosis, prognosis, and treatment difficulty (for example, frequent adjustments in dosing regimens in efforts to prevent rejection of the new cells and susceptibility to infection). We note that the definition of a MS–DRG will not be so specific that every patient is identical, rather, the level of variation is known and predictable. Thus, while the precise resource intensity of a patient cannot be predicted, the average pattern of resource intensity of a group of patients in a MS–DRG can be accurately predicted.

We also appreciate the commenter's feedback on factors to consider for products that are in the pipeline with respect to MS–DRG assignment as a permanent payment mechanism. We agree that there may be distinctions to account for as we continue to gain more experience in the utilization of these therapies and have additional claims data to analyze.

We acknowledge the commenters' concerns that the term ''Other Immunotherapies'' that was proposed for the title of Pre-MDC MS–DRG 018 may be considered broad. While, as several commenters stated in their comments, cellular therapies and gene therapies are an evolving field, the term ''Other Immunotherapies'' is intended to encompass the group of therapies that are currently available and being utilized today (for which codes have been created for reporting in response to industry requests or are being considered for implementation), and to enable appropriate MS–DRG assignment for any future therapies that may also fit into this category and are not specifically identified as a CAR T-cell product, that may become available (for example receive marketing authorization or a newly established procedure code in the ICD–10–PCS classification) during FY 2022. We appreciate the suggestions to consider alternative terminology for the title (description) of Pre-MDC MS–DRG 018 and look forward to continuing to work with stakeholders on this issue in the future. At this time, for FY 2022, we believe it is premature to finalize any of the suggested title revisions by commenters to Pre-MDC MS–DRG 018 that may not fully reflect the various types of therapies and products described by the different procedure codes that are currently assigned or may be considered for assignment there in FY 2022. We also note that any proposed changes to modify the logic for case assignment and/or the title to Pre-MDC MS–DRG 018 would be considered in future rulemaking. We further note that the process of code creation and proposed assignment to the most appropriate MS–DRG exists independently, regardless of whether there is an associated application for a new technology add-on payment for a product or technology submitted for consideration in a given fiscal year. Specifically, requests for a new code(s) or updates to existing codes are addressed through the ICD–10 Coordination and Maintenance Committee meetings where code proposals are presented and the public is provided the opportunity to comment. All codes finalized after the September meeting must be reviewed and are subsequently proposed for assignment under the ICD–10 MS–DRGs through notice and comment rulemaking. Codes that are finalized after the March meeting are also reviewed and subject to our established process of initially reviewing the predecessor codes MS–DRG assignment and designation, while considering other relevant factors as previously described. The codes that are finalized after the March meeting are specifically identified with a footnote in Tables 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes that are made publicly available in association with the final rule via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. The public may provide feedback on these finalized assignments which are then taken into consideration for the following fiscal year. We refer the reader to section II.D.16 of the preamble of this final rule for additional information regarding the ICD–10 Coordination and Maintenance Committee meeting process. Lastly, we note that while some of the commenters opposed the revision to the title and assignment of the new ICD–10–PCS procedure codes to Pre-MDC MS–DRG 018, these commenters did not provide any alternative MS–DRGs for CMS to consider.

In response to concerns involving payment uncertainty, we disagree that modifying Pre-MDC MS–DRG 018 to include other immunotherapies one year after it has been implemented carries a risk of creating additional payment uncertainty around CAR T-cell therapies and volatility in the relative weight for Pre-MDC MS–DRG 018. As stated in section II.E.2.b. of the preamble of the proposed rule and this

final rule, we proposed and are finalizing to maintain the methodology for the relative weight calculation for Pre-MDC MS–DRG 018. We refer the reader to section II.E.2.b. of the preamble of this final rule for the detailed discussion. Since the new procedure codes describing CAR T-cell, non-CAR T-cell or other immunotherapies are effective with discharges on and after October 1, 2021 and based on our understanding that the administration of these therapies continues to be in clinical trials, any claims reporting these new procedure codes containing diagnosis code Z00.6 or having standardized drug charges of less than $373,000 would be excluded from the calculation of the relative weight for Pre-MDC MS–DRG 018. During this timeframe, as additional claims data is made available, we will be better positioned to further evaluate if changes to the current methodology or other modifications to the procedure code assignments and MS–DRG are warranted.

We appreciate the unique process that is involved with the development and production of CAR T-cell therapies, however, under the IPPS, when evaluating appropriate MS–DRG assignment for technologies (for example devices) that are utilized in the performance of a procedure we do not take into consideration how a specific device is manufactured compared to how other similar devices are manufactured. Rather, we analyze and consider the procedure(s) for which the technology is utilized for or in, and the resources involved in the performance of the procedure. As discussed, based on the information to date, we believe that the initial assignment of the listed procedure codes is appropriate. Based on the nature of some comments, it appears commenters were suggesting that CMS apply the criteria that is utilized for the new technology add-on application process when suggesting what factors CMS should consider for MS–DRG assignment of CAR T-cell, non-CAR T-cell, and other immunotherapies. We note that the new technology add-on application criteria is separate and distinct from the code request process and subsequent MS–DRG assignment process.

In response to the commenter who stated there are not any non-CAR T-cell therapy FDA approved products that are anticipated in the near term, we wish to clarify that the proposed and final assignment of a procedure code to a MS–DRG is not dependent upon a products FDA approval. Similarly, the creation of a code to describe a technology that is utilized in the performance of a procedure or service does not require FDA approval of the technology.

With respect to the commenters' recommendation for CMS to continue to assess the appropriateness of the therapies being proposed or finalized to group to Pre-MDC MS–DRG 018, we note that, as discussed in the preamble of the proposed rule and this final rule we use our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment and, consistent with the assignment of those predecessor codes, we propose to classify new procedure codes as shown Table 6B.—New Procedure Codes in association with the proposed rule each year. The procedure codes describing CAR T-cell, non-CAR T-cell or other immunotherapies are effective with discharges on and after October 1, 2021 as shown in Table 6B.—New Procedure Codes associated with this final rule and available via the internet on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*. In connection with the creation of new procedure codes (and diagnosis codes), the MS–DRGs are reviewed and recalibrated on an annual basis to specifically identify changes in utilization and resources, and to allow the opportunity for public comment on proposed changes under the IPPS.

In response to the comment that the term ''immunotherapy'' could describe products that treat a range of conditions, we note that for FY 2022 we are addressing an immediate need to account for any upcoming therapies that may be made available that are not specifically classified as a CAR T-cell therapy to enable appropriate payment and predictability. We note that the ICD–10–CM diagnosis codes identify specific conditions and are available for tracking indications and other purposes. We also note that because MS–DRG 018 is a Pre-MDC, the logic for case assignment is dependent on the procedure codes that are specifically assigned to the logic of the MS–DRG. Therefore, if a particular type of immunotherapy is not specifically described by one of the procedure codes that are listed in the definition (logic) for Pre-MDC MS–DRG 018, then the logic for case assignment to this MS–DRG would not be satisfied and another MS–DRG would be appropriately assigned based on the GROUPER logic (the definition of the MS–DRG).

After consideration of the public comments received, for FY 2022, we are finalizing our proposal to assign the listed procedure codes describing CAR T-cell, non-CAR T-cell and other immunotherapies to Pre-MDC MS–DRG 018 and to modify the title to ''Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies'' to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies.

When additional claims data becomes available for the CAR T-cell, non-CAR T-cell therapies and other immunotherapies for which new procedure codes have been created and are effective October 1, 2021 or that may be created and become effective during FY 2022, we can evaluate that data to determine if further modifications to Pre-MDC MS–DRG 018 are warranted. We plan to continue engaging with stakeholders on additional options for consideration in this field of cellular and gene therapies, such as the creation of new and distinct MS–DRGs and to determine if the creation of a new MDC (Major Diagnostic Category) may be warranted to which unique MS–DRGs could be established and the appropriate corresponding procedure codes could be proposed for assignment.

3. MDC 03 (Diseases and Disorders of Ear, Nose, Mouth and Throat)

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58462 through 58471), we finalized our proposal to create two new base MS–DRGs, 140 and 143, with a three-way severity level split for new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) and new MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). We provided the list of procedure codes that were finalized to define the logic for the new MS–DRGs in Tables 6P.2a, 6P.2b, and 6P.2c associated with the final rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/*. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25095 through 25098), we received two separate but related requests to review and reconsider the MS–DRG assignments for a subset of the procedure codes listed in Table 6P.2a (procedure codes assigned to MS–DRGs 140, 141, and 142) and Table 6P.2b (procedure codes assigned to MS–DRGs 143, 144, and 145). In this section of this rule, we discuss each of these separate, but related requests.

a. Major Head and Neck Procedures

The requestor provided the following procedure codes from Table 6P.2a associated with the FY 2021 IPPS/LTCH PPS final rule for CMS to examine.

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ICD-10-PCS Code	Description
0JB60ZZ	Excision of chest subcutaneous tissue and fascia, open approach
0JB70ZZ	Excision of back subcutaneous tissue and fascia, open approach
0JB80ZZ	Excision of abdomen subcutaneous tissue and fascia, open approach
0W9100Z	Drainage of cranial cavity with drainage device, open approach
0W910ZZ	Drainage of cranial cavity, open approach
0WC10ZZ	Extirpation of matter from cranial cavity, open approach
0WC13ZZ	Extirpation of matter from cranial cavity, percutaneous approach
0WC14ZZ	Extirpation of matter from cranial cavity, percutaneous endoscopic approach

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The requestor stated that the listed procedure codes do not appear appropriately assigned to MS–DRGs 140, 141, and 142. According to the requestor, if any one of the five procedure codes describing a procedure performed on the cranial cavity (0W9100Z, 0W910ZZ, 0WC10ZZ, 0WC13ZZ, or 0WX14ZZ) is assigned in conjunction with a principal diagnosis from MDC 03 (Diseases and Disorders of Ear, Nose, Mouth, and Throat), it appears more appropriate that cases reporting the diagnosis and procedure combination would group to MS–DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively) (for example, ''craniotomy'' MS–DRGs) in MDC 01 (Diseases and Disorders of the Central Nervous System) or to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). The requestor stated that drainage and extirpation from the cranial cavity always involves drilling or cutting through the skull regardless of the approach, therefore the five procedure codes identified warrant assignment to the ''craniotomy'' MS–DRGs. For the three procedure codes describing excision of subcutaneous tissue of chest, back, or abdomen (0JB60ZZ, 0JB70ZZ, and 0JB80ZZ), the requestor stated those codes should group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) because they are not pertinent to the ear, nose, mouth, or throat.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25096 through 25097), we stated that we reviewed this request and noted that the five procedure codes describing procedures performed on the cranial cavity are already assigned to MDC 01 and group to the ''craniotomy'' MS–DRGs (25, 26, and 27) when reported with a principal diagnosis from MDC 01, and are also currently classified as Extensive O.R. procedures, resulting in assignment to MS–DRGs 981, 982, and 983 when any one of the five procedure codes is reported on the claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis. We also noted that in addition to MS–DRGs 25, 26, and 27, MS–DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) and MS–DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) include procedures performed on structures located within the cranial cavity, are included in the range of MS–DRGs known as the ''craniotomy'' MS–DRGs in MDC 01, and the five procedure codes submitted by the requestor describing procedures performed on the cranial cavity are also assigned to these MS–DRGs. We referred the requestor to Appendix E of the ICD–10 MS–DRG Definitions Manual for further discussion of how each procedure code may be assigned to multiple MDCs and MS–DRGs under the IPPS. The ICD–10 MS–DRG Definitions Manual is located on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software.* We also noted that these five procedure codes were previously assigned to MS–DRGs 131 and 132 (Cranial and Facial Procedures with and without CC/MCC, respectively) in MDC 03 under version 37 of the ICD–10 MS–DRGs prior to the restructuring that was finalized effective FY 2021 for MS–DRG 129 (Major Head and Neck Procedures with CC/MCC or Major Device) and MS–DRG 130 (Major Head and Neck Procedures without CC/MCC), MS–DRGs 131 and 132, and MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with and without CC/MCC, respectively).

With regard to the three procedure codes describing excision of subcutaneous tissue of chest, back, or abdomen (0JB60ZZ, 0JB70ZZ, and 0JB80ZZ), the requestor suggested that the codes should group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) specifically because they are not pertinent to the ear, nose, mouth, or throat, however, we noted it is unclear if the requestor was concerned more broadly that the three procedure codes should not group to any MS–DRGs in MDC 03 (Diseases and Disorders of Ear, Nose, Mouth and Throat), given the stated rationale for the request.

We stated in the proposed rule that, upon our review, we believed that the three procedure codes describing excision of subcutaneous tissue of chest, back, and abdomen (0JB60ZZ, 0JB70ZZ, and 0JB80ZZ), which do not describe major head and neck procedures, were inadvertently included in Table 6P.2a for assignment to MS–DRGs 140, 141, and 142. However, we also stated we believe that the codes are appropriate for assignment in MDC 03 and noted that the three procedure codes were previously assigned to MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and

Throat O.R. Procedures with and without CC/MCC, respectively) in MDC 03 prior to the restructuring that was finalized effective FY 2021 for MS–DRGs 129, 130, 131, 132, 133, and 134. We also provided the following clarification in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58470), as stated in the ICD–10 MS–DRG Definitions Manual, ''In each MDC there is usually a medical and a surgical class referred to as ''other medical diseases'' and ''other surgical procedures,'' respectively. The ''other'' medical and surgical classes are not as precisely defined from a clinical perspective. The other classes would include diagnoses or procedures, which were infrequently encountered or not well defined clinically. For example, the ''other'' medical class for the Respiratory System MDC would contain the diagnoses ''other somatoform disorders'' and ''congenital malformation of the respiratory system,'' while the ''other'' surgical class for the female reproductive MDC would contain the surgical procedures ''excision of liver'' (liver biopsy in ICD–9–CM) and ''inspection of peritoneal cavity'' (exploratory laparotomy in ICD–9–CM). The ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC.''

In the proposed rule, we noted that during our review of procedure codes 0JB60ZZ, 0JB70ZZ, and 0JB80ZZ (describing excision of subcutaneous tissue of chest, back, and abdomen, respectively) we also confirmed that these procedures are currently designated as Extensive O.R. procedures. Consistent with other procedure codes on the Non-extensive procedure code list, we stated we do not believe the procedures described by these procedure codes necessarily utilize the resources or have the level of technical complexity as the procedures on the Extensive O.R. procedures list. Therefore, we agreed that the procedure codes describing these procedures would be more appropriately designated as Non-extensive procedures and group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when any one of the three procedure codes is reported on a claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis. We referred the reader to section II.D.10. of the preamble of the proposed rule for further discussion regarding our proposal to reassign these procedure codes from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

Therefore, we proposed to reassign the three procedure codes describing excision of subcutaneous tissue of chest, back, or abdomen (0JB60ZZ, 0JB70ZZ, and 0JB80ZZ) from MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 03 for FY 2022. We refer the reader to section II.D.10. of the preamble of this final rule for further discussion regarding the designation of these codes as Extensive O.R. procedures versus Non-extensive O.R. procedures and our finalized reassignment of these codes from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989 for FY 2022.

Comment: Commenters supported the proposed reassignment of the three procedure codes describing excision of subcutaneous tissue of chest, back, or abdomen from MS–DRGs 140, 141, and 142 to MS–DRGs 143, 144, and 145.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to reassign procedure codes 0JB60ZZ, 0JB70ZZ, and 0JB80ZZ describing excision of subcutaneous tissue of chest, back, or abdomen from MS–DRGs 140, 141, and 142 to MS–DRGs 143, 144, and 145 for FY 2022.

b. Other Ear, Nose, Mouth and Throat O.R. Procedures

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25097 through 25098) and noted earlier, we received two separate but related requests to review and reconsider the MS–DRG assignments for a subset of the procedure codes listed in Table 6P.2a and Table 6P.2b associated with the FY 2021 IPPS/LTCH PPS final rule. In this section of this rule, we discuss the second request related to procedure codes listed in Table 6P.2b associated with the FY 2021 IPPS/LTCH PPS final rule and currently assigned to MS–DRGs 143, 144 and 145.

The requestor provided a list of 82 procedure codes from Table 6P.2b associated with the FY 2021 IPPS/LTCH PPS final rule for CMS to examine. We refer the reader to Table 6P.1d associated with the FY 2022 IPPS/LTCH PPS proposed rule and this final rule and available via the internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/* for the list of procedure codes that were provided by the requestor. According to the requestor, if any one of the 82 procedure codes is assigned in conjunction with a principal diagnosis code from MDC 03, it appears more appropriate that cases reporting the diagnosis and procedure code combination would group to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) versus MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). However, the requestor also stated that of the 82 procedure codes, the following three procedure codes describing control of bleeding in the cranial cavity warrant grouping to MS–DRGs 25, 26, and 27 (for example, ''craniotomy'' MS–DRGs) in MDC 01, for the same reasons previously described in the prior section pertaining to the five other procedures performed on the cranial cavity.

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ICD-10-PCS Code	Description
0W310ZZ	Control bleeding in cranial cavity, open approach
0W313ZZ	Control bleeding in cranial cavity, percutaneous approach
0W314ZZ	Control bleeding in cranial cavity, percutaneous endoscopic approach

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We reviewed this request and similar to the discussion in the prior section for the separate but related request, we noted that the ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. We stated we continue to believe that the 82 procedure codes provided by the requestor are appropriately assigned to MS–DRGs 143, 144, and 145 in MDC 03. With regard to the requestor's assertion that cases reporting any one of the 82 procedure codes would more appropriately group to the MS–DRGs for Extensive O.R. procedures or Non-extensive O.R. procedures when reported in conjunction with a principal diagnosis from MDC 03, we noted that, as shown in Table 6P.2b associated with the FY 2021 IPPS/LTCH PPS final rule, the procedure codes that were finalized for assignment to MS–DRGs 143, 144, and 145 were previously assigned to MS–DRGs 129 and 130, 131 and 132, or 133 and 134 in MDC 03. We also noted that, as discussed in prior rulemaking, cases that contain O.R. procedures will map to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRG 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. For these reasons, we proposed to maintain the current structure for MS–DRGs 143, 144, and 145 for FY 2022.

Comment: A few commenters recommended that CMS reconsider the list of 82 procedure codes assigned to MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC and without CC/MCC, respectively) that were displayed in Table 6P.1d associated with the proposed rule when reported with a principal diagnosis from MDC 03.

The commenters acknowledged that the ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC, however, the commenters stated it is unclear what clinical scenarios would result in certain procedure codes listed being assigned with a diagnosis in MDC 03. The commenters provided the following list of 38 procedure codes as examples of procedures that would not be expected to be performed with a diagnosis from MDC 03.

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ICD-10-PCS Code	Description
02JA4ZZ	Inspection of heart, percutaneous endoscopic approach
02JY0ZZ	Inspection of great vessel, open approach
06HY0DZ	Insertion of intraluminal device into lower vein, open approach
06HY3DZ	Insertion of intraluminal device into lower vein, percutaneous approach
06HY4DZ	Insertion of intraluminal device into lower vein, percutaneous endoscopic approach
07B50ZZ	Excision of right axillary lymphatic, open approach
07B53ZZ	Excision of right axillary lymphatic, percutaneous approach
07B54ZZ	Excision of right axillary lymphatic, percutaneous endoscopic approach
07B60ZZ	Excision of left axillary lymphatic, open approach
07B63ZZ	Excision of left axillary lymphatic, percutaneous approach
07B64ZZ	Excision of left axillary lymphatic, percutaneous endoscopic approach
07T30ZZ	Resection of right upper extremity lymphatic, open approach
07T34ZZ	Resection of right upper extremity lymphatic, percutaneous endoscopic approach
07T40ZZ	Resection of left upper extremity lymphatic, open approach
07T44ZZ	Resection of left upper extremity lymphatic, percutaneous endoscopic approach
07T80ZZ	Resection of right internal mammary lymphatic, open approach
07T84ZZ	Resection of right internal mammary lymphatic, percutaneous endoscopic
07T90ZZ	Resection of left internal mammary lymphatic, open approach
07T94ZZ	Resection of left internal mammary lymphatic, percutaneous endoscopic approach
07TB0ZZ	Resection of mesenteric lymphatic, open approach
07TB4ZZ	Resection of mesenteric lymphatic, percutaneous endoscopic approach
07TF0ZZ	Resection of right lower extremity lymphatic, open approach
07TF4ZZ	Resection of right lower extremity lymphatic, percutaneous endoscopic approach
07TG0ZZ	Resection of left lower extremity lymphatic, open approach
07TG4ZZ	Resection of left lower extremity lymphatic, percutaneous endoscopic approach
0DJ04ZZ	Inspection of upper intestinal tract, percutaneous endoscopic approach
0F900ZX	Drainage of liver, open approach, diagnostic
0F910ZX	Drainage of right lobe liver, open approach, diagnostic
0F920ZX	Drainage of left lobe liver, open approach, diagnostic
0FB00ZX	Excision of liver, open approach, diagnostic
0FB10ZX	Excision of right lobe liver, open approach, diagnostic
0FB20ZX	Excision of left lobe liver, open approach, diagnostic
0PB40ZZ	Excision of thoracic vertebra, open approach
0PB43ZZ	Excision of thoracic vertebra, percutaneous approach
0PB44ZZ	Excision of thoracic vertebra, percutaneous endoscopic approach
0QB00ZZ	Excision of lumbar vertebra, open approach
0QB03ZZ	Excision of lumbar vertebra, percutaneous approach
0QB04ZZ	Excision of lumbar vertebra, percutaneous endoscopic approach

BILLING CODE 4120–01–C

Another commenter requested transparency for the logic and data for the exclusion of the 82 procedure codes and suggested that CMS may not have any data for these procedures within MS–DRGs 143, 144, and 145 that were created in FY 2021.

Response: We appreciate the commenters' feedback and acknowledge that the listed procedure codes would not appear to be clinically indicated specifically for diagnoses in MDC 03. The commenter is correct that it is too soon to have data available for the listed procedure codes under MS–DRGs 143, 144, and 145 that were created effective FY 2021. However, in our analysis of the FY 2018 MedPAR data that was studied in our initial review of MDC 03 in consideration of potential restructuring, for MS–DRG 133 (currently MS–DRG 144), we identified one case reporting procedure code 0DJ04ZZ (Inspection of upper intestinal tract, percutaneous endoscopic approach) with an average length of stay of 14 days and average costs of $5,728 and one case reporting procedure code 0FB00ZX (Excision of liver, open approach, diagnostic) with an average length of stay of 17 days and average costs of $32,642. We continued to believe that these procedures, in addition and/or including the 38 procedure codes listed that are now the subject of commenters' concerns, appropriate to maintain in the logic for case assignment to the ''other'' surgical MS–DRGs in MDC 03. However, as a result of the ongoing concerns expressed by commenters specifically regarding the assignment of the 38 listed procedure codes and the suggestion that CMS should reconsider the current MS–DRG assignment, we determined it may be helpful to provide the comparable translations under ICD–9–CM for commenters to better understand how these 38 procedures were initially grouped to the ICD–10 MS–DRGs as a result of replication during the conversion from ICD–9 to ICD–10 based MS–DRGs. We refer the reader to Table

6P.1m for findings from our analysis of the 38 listed procedure codes, which indicates how these procedures were classified under ICD–10–PCS based on the comparable translations under ICD–9–CM resulting in the current MS–DRG assignment. We note that we were unable to fully evaluate the 82 procedure codes and believe it may be advantageous to evaluate further when claims data becomes available under the restructured MS–DRGs (143, 144, and 145) that were effective with discharges beginning FY 2021.

In response to the commenter who requested transparency for the logic, we note that the GROUPER logic for all the MS–DRGs is made publicly available in the ICD–10 MS–DRG Definitions Manual via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software*.

After consideration of the public comments we received, we are finalizing to maintain the assignment of the listed 82 procedure codes to MS–DRGs 143, 144, and 145 for FY 2022. We will continue to review the appropriateness of procedure code assignment to these MS–DRGs in connection with our broader comprehensive procedure code analysis.

As noted in the proposed rule, with regard to the three procedure codes describing control of bleeding in the cranial cavity (0W310ZZ, 0W313ZZ, and 0W314ZZ), and the requestor's suggestion that the codes should group to MS–DRGs 25, 26, and 27 in MDC 01, we consulted with our clinical advisors who stated these procedures are consistent with the existing procedure codes included in the logic for case assignment to MS–DRGs 25, 26, and 27. We refer the reader to section II.D.10. of the preamble of the proposed rule and this final rule for further discussion of this request, as well as the finalized assignment of these codes to MS–DRGs 23, 24, 25, 26, and 27 for FY 2022.

4. MDC 04 (Diseases and Disorders of the Respiratory System)

a. Bronchiectasis

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25098), we discussed a request we received to reassign cases reporting diagnosis codes describing bronchiectasis from MS–DRGs 190, 191, and 192 (Chronic Obstructive Pulmonary Disease with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 177, 178, and 179 (Respiratory Infections and Inflammation with MCC, with CC, and without CC/MCC, respectively). Bronchiectasis is described by the following diagnosis codes:

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ICD-10-CM Code	Description
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
Q33.4	Congenital bronchiectasis

BILLING CODE 4120–01–C

According to the requestor, the underlying pathophysiology of bronchiectasis is more similar to cystic fibrosis than it is to chronic obstructive pulmonary disease (COPD). The requestor stated that in bronchiectasis, there is an inciting event that creates scarring in the lung which prevents the lung from clearing out mucous like it normally would. The accumulation of abnormal mucous results in an environment conducive to bacterial growth and commonly found bacteria in this setting is very similar to those of cystic fibrosis with staphylococcus aureus, pseudomonas aeruginosa, and non-tuberculous mycobacterium. The requestor reported that when patients develop an exacerbation of bronchiectasis, this is because of a buildup of mucous compounded by overwhelming growth of the previously discussed bacteria. The requestor also stated that patients admitted to the hospital for bronchiectasis exacerbation are treated aggressively with intravenous (IV) antibiotics to suppress the bacterial infection in combination with airway clearance therapies. The requestor further stated that, unlike in an acute COPD exacerbation, these patients do not always require steroids as there is not necessarily airway reactivity.

The requestor maintained that the underlying reason for admission to the hospital for these patients is the bacterial infection component of the exacerbation, with the standard course of treatment for these pulmonary bacterial infections averaging a minimum of 10–14 days due to the slow growing nature of the bacteria commonly encountered in these patients.

We stated in the FY 2022 IPPS/LTCH PPS proposed rule that we reviewed this request and believed that bronchiectasis is appropriately assigned to MS–DRGs 190, 191, and 192 (Chronic Obstructive Pulmonary Disease with MCC, with CC, and without CC/MCC, respectively) because bronchiectasis, like COPD, is a chronic condition. We noted that with respect to the requestor's comments, cystic fibrosis, a genetic disease that affects mucous producing cells resulting in recurring lung infections, can lead to bronchiectasis. However, our clinical advisors indicated that the cause of bronchiectasis can be multifactorial or even remain undefined. Regardless of the cause, when present, bronchiectasis is an irreversible chronic pulmonary condition due to abnormal change to or destruction of normal pulmonary anatomy (the major bronchi and bronchiole walls), resulting in impaired air movement in and out of the lungs. COPD, regardless of the cause (smoking, pollution, other exposures), is a chronic pulmonary condition due to change/destruction of normal pulmonary anatomy, resulting in impaired air movement in and out of the lungs. Both bronchiectasis and COPD patients have abnormal pulmonary function tests and abnormal anatomic findings on chest x-ray and/or chest CT. Therefore, for these reasons, we proposed to maintain the structure of MS–DRGs 190, 191, and 192 for FY 2022.

Comment: Commenters agreed with our proposal to maintain the structure of MS–DRGs 190, 191, and 192.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the structure of MS–DRGs 190, 191, and 192 for FY 2022.

b. Major Chest Procedures

In the FY 2020 IPPS/LTCH PPS proposed (84 FR 19234) and final rules (84 FR 42148), we stated that in review of the procedures that are currently assigned to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively) and 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), that further refinement of these MS–DRGs may be warranted. In this section of this rule, we discuss our review of the procedures and restructuring these MS–DRGs for FY 2022.

We began our review of MS–DRGs 163, 164, 165, 166, 167, and 168 by first examining all the procedures currently assigned to these MS–DRGs. We referred the reader to the ICD–10 MS–DRG Definitions Manual Version 38.1, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* for complete documentation of the GROUPER logic for MS–DRGs 163, 164, 165, 166, 167, and 168.

We stated in the proposed rule that in our review of the procedures currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168, we found 17 procedure codes in MS–DRGs 163, 164, and 165 describing laser interstitial thermal therapy (LITT) of body parts that do not describe areas within the respiratory system, which would not be clinically appropriate to maintain in the logic. These procedure codes are listed in the following table.

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ICD-10-PCS Code	Description
D0Y6KZZ	Laser interstitial thermal therapy of spinal cord
D0Y7KZZ	Laser interstitial thermal therapy of peripheral nerve
DDY0KZZ	Laser interstitial thermal therapy of esophagus
DDY1KZZ	Laser interstitial thermal therapy of stomach
DDY2KZZ	Laser interstitial thermal therapy of duodenum
DDY3KZZ	Laser interstitial thermal therapy of jejunum
DDY4KZZ	Laser interstitial thermal therapy of ileum
DDY5KZZ	Laser interstitial thermal therapy of colon
DDY7KZZ	Laser interstitial thermal therapy of rectum
DDY8KZZ	Laser interstitial thermal therapy of anus
DFY1KZZ	Laser interstitial thermal therapy of gallbladder
DFY2KZZ	Laser interstitial thermal therapy of bile ducts
DFY3KZZ	Laser interstitial thermal therapy of pancreas
DGY2KZZ	Laser interstitial thermal therapy of adrenal glands
DMY0KZZ	Laser interstitial thermal therapy of left breast
DMY1KZZ	Laser interstitial thermal therapy of right breast
DVY0KZZ	Laser interstitial thermal therapy of prostate

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During our review of these 17 procedure codes, we identified additional MDCs and MS–DRG assignments that are also not clinically appropriate to maintain in the logic because the body parts described by the codes are not consistent with the organ system, etiology or clinical specialty of the MDC to which the procedure code is currently assigned. For example, 16 of the 17 procedure codes (all except procedure code DVY0KZZ) are included in the logic for case assignment to MDC 12 (Diseases and Disorders of the Male Reproductive System) in MS–DRGs 715 and 716 (Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively) and MS–DRGs 717 and 718 (Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively) which is not clinically appropriate. Therefore, we proposed to reassign these 17 procedure codes from their current MS–DRG assignments in MDC 04, and from the additional MDCs and MS–DRGs identified during our review that were found to be clinically inappropriate, to their clinically appropriate MDC and MS–DRGs as shown in Table 6P.2b associated with the proposed rule and this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*).

Comment: Commenters agreed with the proposed reassignment of the listed procedure codes as shown in Table 6P.2b associated with the proposed rule describing LITT of various body parts to the proposed more clinically appropriate MDCs and MS–DRGs. However, a commenter suggested that CMS consider reassignment of code D0Y6KZZ to MS–DRGs 28, 29, and 30 (Spinal Procedures with MCC, with CC or Spinal Neurostimulators and without CC/CC, respectively) rather than MS–DRGs 40, 41, and 42 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC and without CC/MCC, respectively) as being more clinically and anatomically homogenous.

Response: We thank the commenters for their support. In response to the commenter who suggested that CMS consider reassignment of code D0Y6KZZ to MS–DRGs 28, 29, and 30 rather than MS–DRGs 40, 41, and 42 we note that our clinical advisors continue to believe this is an appropriate

assignment to MS–DRGs 40, 41, and 42 because the resources involved in the performance of a LITT procedure of the spinal cord (code D0Y6KZZ) clinically align more appropriately with the resources involved in the performance of stereotactic radiosurgery of spinal cord procedures currently assigned to MS–DRGs 40, 41, and 42 (procedure codes D026DZZ, D026HZZ, and D026JZZ).

We also note that, as discussed in section II.D.10. of the preamble of the proposed rule and this final rule, we identified additional procedure codes describing LITT of various body parts, in addition to the 17 procedure codes listed earlier in this section. The 14 additional procedure codes are:

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ICD-10-PCS Code	Description
D0Y0KZZ	Laser interstitial thermal therapy of brain
D0Y1KZZ	Laser interstitial thermal therapy of brain stem
DBY0KZZ	Laser interstitial thermal therapy of trachea
DBY1KZZ	Laser interstitial thermal therapy of bronchus
DBY2KZZ	Laser interstitial thermal therapy of lung
DBY5KZZ	Laser interstitial thermal therapy of pleura
DBY6KZZ	Laser interstitial thermal therapy of mediastinum
DBY7KZZ	Laser interstitial thermal therapy of chest wall
DBY8KZZ	Laser interstitial thermal therapy of diaphragm
DFY0KZZ	Laser interstitial thermal therapy of liver
DGY0KZZ	Laser interstitial thermal therapy of pituitary gland
DGY1KZZ	Laser interstitial thermal therapy of pineal body
DGY4KZZ	Laser interstitial thermal therapy of parathyroid glands
DGY5KZZ	Laser interstitial thermal therapy of thyroid

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As these codes also describe laser interstitial thermal therapy (LITT) of various body parts, we conducted further review of the MDC and MS–DRG assignments of these 14 procedure codes consistent with our initial review of the 17 procedure codes, and determined that clinically inappropriate assignments also exist or that the current MS–DRG assignment is not in alignment with the resources that are utilized in the performance of the LITT procedure. For example, we examined procedure codes D0Y0KZZ and D0Y1KZZ describing LITT of brain and brain stem, respectively, that are currently assigned to the ''craniotomy'' MS–DRGs 23, 24, 25 26, and 27 in MDC 01 (Diseases and Disorders of the Central Nervous System). The technique to perform the LITT procedure on these structures is considered minimally invasive and does not involve a craniotomy, therefore, continued assignment to the craniotomy MS–DRGs is not clinically appropriate. While we agree that these procedures are appropriately assigned to MDC 01, similar to our review for procedure code D0Y6KZZ describing LITT of spinal cord, we believe it is more appropriate for the procedures described by codes D0Y0KZZ and D0Y1KZZ to be reassigned to MS–DRGs 40, 41, and 42. We then examined procedure codes DBY0KZZ, DBY1KZZ, DBY2KZZ, DBY5KZZ, DBY6KZZ, DBY7KZZ, and DBY8KZZ describing LITT of respiratory structures including the trachea, bronchus, lung, pleura, mediastinum, chest wall, and diaphragm, respectively, that are currently assigned to the ''major chest procedures'' MS–DRGs 163, 164, and 165. While we agree that these procedures are appropriately assigned to MDC 04, we do not believe LITT of these respiratory structures utilize the same resources or require the same level of complexity as the other procedures currently defined in the GROUPER logic as ''major chest procedures'' since, as noted previously, LITT is considered a minimally invasive procedure and there are no large incisions with extensive muscle dissection. For these reasons, we believe it is more appropriate for the procedure codes describing LITT of respiratory structures to be reassigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

After consideration of the public comments we received and based on the analysis described previously, we are finalizing our proposal, with modification, to reassign the 31 listed procedure codes as shown in Table 6P.2b associated with this final rule describing LITT of various body parts to the more clinically appropriate MDCs and MS–DRGs for FY 2022.

During our review of the procedure codes describing LITT of various body parts we also confirmed that these procedures are currently designated as Extensive O.R. procedures. We do not believe the procedures described by these procedure codes necessarily utilize the resources or have the level of technical complexity as the other procedures on the Extensive O.R. procedures list. We stated in the proposed rule that we believe that the procedure codes describing these procedures would be more appropriately designated as Non-extensive procedures and group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when any one of the procedure codes is reported on a claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis. We refer the reader to section II.D.10. of the preamble of the proposed rule and this final rule for further discussion regarding reassignment of these procedure codes from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with

MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

We also identified five procedure codes describing repair of the esophagus procedures currently assigned to MS–DRGs 163, 164, and 165 that would not be clinically appropriate to maintain in the logic. The procedure codes are 0DQ50ZZ (Repair esophagus, open approach), 0DQ53ZZ (Repair esophagus, percutaneous approach), 0DQ54ZZ (Repair esophagus, percutaneous endoscopic approach), 0DQ57ZZ (Repair esophagus, via natural or artificial opening), and 0DQ58ZZ (Repair esophagus, via natural or artificial opening endoscopic), and are currently assigned to the following MDCs and MS–DRGs.

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MDC	Description	MS-DRG	Description
03	Diseases and Disorders of the Ear, Nose, Mouth and Throat	143	Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC
		144	Other Ear, Nose, Mouth and Throat O.R. Procedures with CC
		145	Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC
06	Diseases and Disorders of the Digestive System	326	Stomach, Esophageal and Duodenal Procedures with MCC
		327	Stomach, Esophageal and Duodenal Procedures with CC
		328	Stomach, Esophageal and Duodenal Procedures without CC/MCC
17	Myeloproliferative Diseases and Disorders, and Poorly Differentiated Neoplasms	820	Lymphoma and Leukemia with Major O.R. Procedures with MCC
		821	Lymphoma and Leukemia with Major O.R. Procedures with CC
		822	Lymphoma and Leukemia with Major O.R. Procedures without CC/MCC
		826	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC
		827	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with CC

		828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures without CC/MCC
21	Injuries, Poisonings and Toxic Effects of Drugs	907	Other O.R. Procedures for Injuries with MCC
		908	Other O.R. Procedures for Injuries with CC
		909	Other O.R. Procedures for Injuries without CC/MCC
24	Multiple Significant Trauma	957	Other O.R. Procedures for Multiple Significant Trauma with MCC
		958	Other O.R. Procedures for Multiple Significant Trauma with CC
		959	Other O.R. Procedures for Multiple Significant Trauma without CC/MCC

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We stated that the five procedure codes describing repair of esophagus procedures are not clinically coherent with the other procedures in MS–DRGs 163, 164, and 165 that describe procedures performed on major chest structures. Therefore, we proposed to remove procedure codes 0DQ50ZZ, 0DQ53ZZ, 0DQ54ZZ, 0DQ57ZZ, and 0DQ58ZZ from the logic in MDC 04 for FY 2022.

Comment: Commenters agreed with the proposal to remove procedure codes 0DQ50ZZ, 0DQ53ZZ, 0DQ54ZZ, 0DQ57ZZ, and 0DQ58ZZ from the logic in MDC 04.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove procedure codes 0DQ50ZZ, 0DQ53ZZ, 0DQ54ZZ, 0DQ57ZZ, and 0DQ58ZZ describing repair of the esophagus from the logic in MDC 04 for FY 2022.

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25102), during our review of procedure codes 0DQ50ZZ, 0DQ53ZZ, 0DQ54ZZ, 0DQ57ZZ, and 0DQ58ZZ (describing repair of esophagus procedures) we also confirmed that these procedures are currently designated as Extensive O.R. procedures. We stated we do not believe the procedures described by procedure codes 0DQ53ZZ, 0DQ57ZZ, and 0DQ58ZZ necessarily utilize the resources or have the level of technical complexity as the other procedures on the Extensive O.R. procedures list. We further stated we believe that the procedure codes describing these procedures would be more appropriately designated as Non-extensive procedures and group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when any one of the three procedure codes is reported on a claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis. We refer the reader to section II.D.10. of the preamble of the proposed rule and this final rule for further discussion regarding reassignment of these procedure codes from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

Next, we examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for all cases in MS–DRGs 163, 164, 165, 166, 167, and 168. Our findings are shown in the following tables.

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March 2020 Update of the FY 2019 MedPAR File			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
163	10,851	11.7	$34,904
164	15,743	5.4	$19,258
165	8,144	3.1	$14,120
166	10,151	10.6	$26,677
167	6,483	5.0	$13,517
168	2,420	2.6	$10,117

September 2020 Update of the FY 2020 MedPAR File			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
163	9,227	11.1	$35,694
164	13,121	5.1	$19,786
165	6,339	3.0	$14,991
166	8,213	10.7	$27,939
167	4,889	5.0	$14,288
168	1,726	2.5	$10,566

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As shown in the tables, there were a higher number of cases reported in MS–DRGs 163, 164, 165, 166, 167, and 168 from the March 2020 update of the FY 2019 MedPAR file in comparison to the September 2020 update of the FY 2020 MedPAR file and overall, the cases reported have comparable average lengths of stay and comparable average costs for both fiscal years.

We then examined claims data from both the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for MS–DRGs 163, 164, 165, 166, 167, and 168 to compare costs, complexity of service and clinical coherence for each procedure code currently assigned to these MS–DRGs to assess any potential reassignment of the procedures. We refer the reader to Table 6P.1e and Table 6P.1f associated with the proposed rule and this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the detailed claims data analysis. Table 6P.1e contains the data analysis findings of procedure codes currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168 from the March 2020 update of the FY 2019 MedPAR file and Table 6P.1f contains the data analysis findings of procedure codes currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168 from the September 2020 update of the FY 2020 MedPAR file. We note that if a procedure code that is currently assigned to MS–DRGs 163, 164, 165, 166, 167, or 168 is not displayed, it is because there were no cases found reporting that code in the assigned MS–DRG.

As shown in Table 6P.1e and Table 6P.1f associated with the proposed rule and this final rule, in our examination of the claims data from both the March 2020 update of the FY 2019 MedPAR file and September 2020 update of the FY 2020 MedPAR file, we found there is wide variation in the volume, length of stay, and average costs for the procedures currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168. There were several instances in which only one occurrence of a procedure was reported with a procedure code from MS–DRGs 163, 164, 165, 166, 167, or 168, and the average length of stay for these specific cases ranged from 1 day to 97 days. For example, in the analysis of claims data from the March 2020 update of the FY 2019 MedPAR file, during our review of MS–DRG 163, we found 153 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 2 days to 65 days and the average costs ranging from $3,760 to $195,447 for these cases. For MS–DRG 164, we found 145 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 28 days and the average costs ranging from $1,886 to $137,810 for these cases. For MS–DRG 165, we found 111 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 23 days and the average costs ranging from $2,656 to $73,092 for these cases. For MS–DRG 166, we found 150 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 61 days and the average costs ranging from $3,230 to $246,679 for these cases. For MS–DRG 167, we found 110 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 23 days and the average costs ranging from $2,058 to $149,220 for these cases. For MS–DRG 168, we found 68 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 18 days and the average costs ranging from $2,033 to $35,576 for these cases.

Our analysis of the claims data from the September 2020 update of the FY 2020 MedPAR file resulted in similar findings to those from the March 2020 update of the FY 2019 MedPAR file; there were several instances in which only one occurrence of a procedure was reported with a procedure code from MS–DRGs 163, 164, 165, 166, 167, or 168. During our review of MS–DRG 163, we found 139 procedures for which only one occurrence of the procedure

was reported with the average length of stay ranging from 2 days to 97 days and the average costs ranging from $5,697 to $205,696 for these cases. For MS–DRG 164, we found 122 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 35 days and the average costs ranging from $3,204 to $120,128 for these cases. For MS–DRG 165, we found 92 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 16 days and the average costs ranging from $2,682 to $164,014 for these cases. For MS–DRG 166, we found 141 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 45 days and the average costs ranging from $3,230 to $246,679 for these cases. For MS–DRG 167, we found 105 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 22 days and the average costs ranging from $2,150 to $112,465 for these cases. For MS–DRG 168, we found 72 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 9 days and the average costs ranging from $1,563 to $76,061 for these cases.

Our clinical advisors reviewed the procedures currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168 to identify the patient attributes that currently define each of these procedures and to group them with respect to complexity of service and resource intensity. This process included separating the procedures according to the surgical approach (open, percutaneous, percutaneous endoscopic, via natural or artificial opening, via natural or artificial opening endoscopic, and external).

We also considered the claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for MS–DRGs 163, 164, 165, 166, 167, and 168 to further analyze the average length of stay and average costs for the cases reporting procedures assigned to any one of these MS–DRGs as well as clinical coherence for these cases. For example, procedures that we believe represent greater treatment difficulty and reflect a class of patients who are similar clinically with regard to consumption of hospital resources were grouped separately from procedures that we believe to be less complex but still reflect patients who are similar clinically with regard to consumption of hospital resources. This approach differentiated the more complex procedures, such as procedures performed on the sternum and ribs (for example, major chest) from the less complex procedures such as bypass procedures performed on peripheral vessels or diagnostic biopsies.

We stated in the FY 2022 IPPS/LTCH PPS proposed rule that as an initial step in our proposed restructuring of these MS–DRGs, we identified the following 26 procedure codes that are currently assigned to MS–DRGs 166, 167, and 168 that we believe represent procedures performed on structures that align more appropriately with the procedures assigned to MS–DRGs 163, 164, and 165 that describe major chest procedures.

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ICD-10-PCS Code	Description
02QP4ZZ	Repair pulmonary trunk, percutaneous endoscopic approach
02QQ0ZZ	Repair right pulmonary artery, open approach
02QQ4ZZ	Repair right pulmonary artery, percutaneous endoscopic approach
02QR0ZZ	Repair left pulmonary artery, open approach
02QR4ZZ	Repair left pulmonary artery, percutaneous endoscopic approach
02QW0ZZ	Repair thoracic aorta, descending, open approach
02QW4ZZ	Repair thoracic aorta, descending, percutaneous endoscopic approach
02QX0ZZ	Repair thoracic aorta, ascending/arch, open approach
02QX4ZZ	Repair thoracic aorta, ascending/arch, percutaneous endoscopic approach
0PH000Z	Insertion of rigid plate internal fixation device into sternum, open approach
0PH004Z	Insertion of internal fixation device into sternum, open approach
0PH040Z	Insertion of rigid plate internal fixation device into sternum, percutaneous endoscopic approach
0PH044Z	Insertion of internal fixation device into sternum, percutaneous endoscopic approach
0PH144Z	Insertion of internal fixation device into 1 to 2 ribs, percutaneous endoscopic approach
0PH204Z	Insertion of internal fixation device into 3 or more ribs, open approach
0PH244Z	Insertion of internal fixation device into 3 or more ribs, percutaneous endoscopic approach
0PQ00ZZ	Repair sternum, open approach
0PQ04ZZ	Repair sternum, percutaneous endoscopic approach
0PS10ZZ	Reposition 1 to 2 ribs, open approach
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach
0PS204Z	Reposition 3 or more ribs with internal fixation device, open approach
0PS20ZZ	Reposition 3 or more ribs, open approach
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach
0PT00ZZ	Resection of sternum, open approach
0PT10ZZ	Resection of 1 to 2 ribs, open approach
0PT20ZZ	Resection of 3 or more ribs, open approach

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We analyzed claims data from the March 2020 update of the FY 2019 MedPAR file for the listed procedure codes in MS–DRGs 166, 167, and 168. We noted that if a listed procedure code is not displayed, it is because there were no cases found reporting that code among MS–DRGs 166, 167, and 168. Our findings are shown in the following table.

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ICD-10-PCS Code	Description	Frequency	Average Length of Stay	Average Costs
02QR0ZZ	Repair left pulmonary artery, open approach	1	1	$3,463
02QW0ZZ	Repair thoracic aorta, descending, open approach	1	15	$46,829
0PH204Z	Insertion of internal fixation device into 3 or more ribs, open approach	5	6.4	$23,032
0PQ00ZZ	Repair sternum, open approach	1	11	$18,388
0PS10ZZ	Reposition 1 to 2 ribs, open approach	2	6.0	$22,019
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach	2	8.5	$25,123
0PS204Z	Reposition 3 or more ribs with internal fixation device, open approach	288	9.47	$44,510
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach	3	5.67	$37,069
0PT10ZZ	Resection of 1 to 2 ribs, open approach	9	10.58	$22,901
0PT20ZZ	Resection of 3 or more ribs, open approach	2	73.5	$183,630

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We then analyzed claims data from the September 2020 update of the FY 2020 MedPAR file for the listed procedure codes in MS–DRGs 166, 167, and 168. We noted that if a listed procedure code is not displayed, it is because there were no cases found reporting that code among MS–DRGs 166, 167, and 168. Our findings are shown in the following table.

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ICD-10-PCS Code	Description	Frequency	Average Length of Stay	Average Costs
02QX0ZZ	Repair thoracic aorta, ascending/arch, open approach	2	20	$134,670
0PH000Z	Insertion of rigid plate internal fixation device into sternum, open approach	2	11.5	$58,192
0PH004Z	Insertion of internal fixation device into sternum, open approach	4	18.5	$34,164
0PH044Z	Insertion of internal fixation device into sternum, percutaneous endoscopic approach	1	6	$19,501
0PH144Z	Insertion of internal fixation device into 1 to 2 ribs, percutaneous endoscopic approach	3	7.7	$26,846
0PH204Z	Insertion of internal fixation device into 3 or more ribs, open approach	18	10.1	$39,546
0PH244Z	Insertion of internal fixation device into 3 or more ribs, percutaneous endoscopic approach	1	10	$40,069
0PQ00ZZ	Repair sternum, open approach	5	6.4	$31,049
0PS10ZZ	Reposition 1 to 2 ribs, open approach	1	16	$147,493
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach	3	8.3	$25,944
0PS204Z	Reposition 3 or more ribs with internal fixation device, open approach	344	9.6	$48,340
0PS20ZZ	Reposition 3 or more ribs, open approach	1	12	$22,535
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach	5	5.2	$38,618
0PT00ZZ	Resection of sternum, open approach	1	3.0	$7,072
0PT10ZZ	Resection of 1 to 2 ribs, open approach	7	7.9	$29,222
0PT20ZZ	Resection of 3 or more ribs, open approach	3	13	$32,933

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We referred the reader to Tables 6P.1e and 6P.1f for detailed claims data for the previously listed procedures in MS–DRGs 163, 164, 165, 166, 167, and 168 from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, respectively, and noted in the proposed rule that while some of the 26 listed procedure codes identified in MS–DRGs 166, 167, and 168 may not have been reported in either year's MedPAR claims data or only had one occurrence in which the procedure was reported, we believe these procedures described by the listed 26 procedure codes are clinically coherent with the other procedures that are currently assigned to MS–DRGs 163, 164, and 165. For example, in our analysis of the March 2020 update of the FY 2019 MedPAR file, as shown in the table, we found procedure code 02QW0ZZ reported with one occurrence with an average length of stay of 15 days and average costs of $46,829. Despite finding only one case, we stated that we believe procedures described by this procedure code, as well as related procedure codes describing procedures performed on the great vessels, are more clinically coherent with the procedures assigned to MS–DRGs 163, 164, and 165 and align more appropriately with the average length of stay and average costs of those MS–DRGs. Similarly, in our analysis of the September 2020 update of the FY 2020 MedPAR file, as shown in the table, we found procedure code 0PS204Z reported with 344 occurrences with an average length of stay of 9.6 days and average costs of $48,340. We stated that we believe procedures described by this procedure code, as well as related procedure codes describing procedures performed to repair or resect the ribs, are more clinically coherent with the procedures

assigned to MS–DRGs 163, 164, and 165 and also align more appropriately with the average length of stay and average costs of those MS–DRGs.

As a result of our preliminary review of MS–DRGs 163, 164, 165, 166, 167, and 168, for FY 2022, we proposed the reassignment of the listed 26 procedure codes (9 procedure codes describing repair of pulmonary or thoracic structures, and 17 procedure codes describing procedures performed on the sternum or ribs) from MS–DRGs 166, 167, and 168 to MS–DRGs 163, 164, and 165 in MDC 04. We stated that our data analysis shows that for the cases reporting any one of the 26 procedure codes, generally, they have an average length of stay and average costs that appear more consistent with the average length of stay and average costs of cases in MS–DRGs 163, 164, and 165. Our clinical advisors also agreed that these procedures clinically align with the other procedures that are currently assigned to MS–DRGs 163, 164, and 165. We referred the reader to Table 6P.2c associated with the proposed rule for the list of procedure codes we proposed for reassignment from MS–DRGs 166, 167, and 168 to MS–DRGs 163, 164, and 165 in MDC 04.

Comment: Commenters supported the proposed reassignment of the listed 26 procedure codes from MS–DRGs 166, 167, and 168 to MS–DRGs 163, 164, and 165 in MDC 04.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to reassign the listed 26 procedure codes (9 procedure codes describing repair of pulmonary or thoracic structures, and 17 procedure codes describing procedures performed on the sternum or ribs), as listed in Table 6P.2c associated with this final rule, from MS–DRGs 166, 167, and 168 to MS–DRGs 163, 164, and 165 in MDC 04 for FY 2022.

As discussed in the proposed rule, after this initial review of all the procedures currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168, in combination with the results of the data analysis as reflected in Tables 6P.1e and 6P.1f, our clinical advisors support a phased restructuring of these MS–DRGs. We believe further analysis of the procedures assigned to these MS–DRGs is warranted based on the creation of new procedure codes that have been assigned to these MS–DRGs in recent years for which claims data are not yet available and the need for additional time to examine the procedures currently assigned to those MS–DRGs by clinical intensity, complexity of service and resource utilization. We will continue to evaluate the procedures assigned to these MS–DRGs as additional claims data become available.

5. MDC 05 (Diseases and Disorders of the Circulatory System)

a. Short-Term External Heart Assist Device

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25106 through 25115), Impella® Ventricular Support Systems are temporary heart assist devices intended to support blood pressure and provide increased blood flow to critical organs in patients with cardiogenic shock, by drawing blood out of the heart and pumping it into the aorta, partially or fully bypassing the left ventricle to provide adequate circulation of blood (replace or supplement left ventricle pumping) while also allowing damaged heart muscle the opportunity to rest and recover in patients who need short-term support for up to 6 days. The ICD–10–PCS codes that describe the insertion of Impella® heart assist devices are currently assigned to MS–DRG 215 (Other Heart Assist System Implant). We referred the reader to the ICD–10 MS–DRG Definitions Manual Version 38.1, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRG 215.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41159 through 41170), we discussed public comments that recommended that CMS continue to monitor the data in MS–DRG 215 for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of procedures utilizing heart assist devices. Our data analysis showed a wide range in the average length of stay and the average costs for cases reporting procedures that involve a biventricular short-term external heart assist system versus a short-term external heart assist system. We noted we were aware that the AHA published Coding Clinic advice that clarified coding and reporting for certain external heart assist devices due to the technology being approved for new indications but the claims data current at that time did not yet reflect that updated guidance. We also noted that there had been recent updates to the descriptions of the codes for heart assist devices. The qualifier ''intraoperative'' was added effective October 1, 2017 (FY 2018) to the procedure codes describing the insertion of short-term external heart assist system procedures to distinguish between procedures where the device was only used intraoperatively and was removed at the conclusion of the procedure versus procedures where the device was not removed at the conclusion of the procedure and for which that qualifier would not be reported. We agreed with the commenters that continued monitoring of the data and further analysis was necessary prior to proposing any modifications to MS–DRG 215 and finalized our proposal to maintain the current structure of MS–DRG 215 for FY 2019.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42167) we discussed public comments on our proposals related to recalibration of the FY 2020 relative weights and the changes in relative weights from FY 2019. Several commenters expressed concern about significant reductions to the relative weight for MS–DRG 215. Commenters stated that the reduction in the proposed relative weight was 29 percent, the largest decrease of any MS–DRG; commenters also noted that the cumulative decrease to the relative weight for MS–DRG 215 would be 43 percent since FY 2017. Commenters stated that the proposed relative weights would result in significant underpayments to facilities, which would in turn limit access to heart assist devices. After reviewing the comments received and the data used in our ratesetting calculations, we acknowledged an outlier circumstance where the weight for a MS–DRG was seeing a significant reduction for each of the 3 years since CMS began using the ICD–10 data in calculating the relative weights. Therefore, for the reasons discussed in the FY 2020 final rule, we adopted a temporary one-time measure for FY 2020 where the FY 2020 relative weight was set equal to the FY 2019 relative weight, which in turn had been set equal to the FY 2018 relative weight.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58598) we again acknowledged an outlier circumstance where the weight for MS–DRG 215 was seeing a significant reduction for each of the 4 years since CMS began using the ICD–10 data in calculating the relative weights. We stated while we would ordinarily consider this weight change to be appropriately driven by the underlying data, given the comments received, and in an abundance of caution because this may be the MS–DRG assigned when a hospital provides temporary right ventricular support for

up to 14 days in critical care patients for the treatment of acute right heart failure or decompensation caused by complications related to COVID–19, including pulmonary embolism, we adopted a temporary one-time measure for FY 2021 for MS–DRG 215. Specifically, we set the 2021 relative weight for MS–DRG 215 equal to the average of the FY 2020 relative weight and the otherwise applicable FY 2021 weight.

For the FY 2022 IPPS/LTCH PPS proposed rule, we received a request to reassign certain cases reporting procedure codes describing the insertion of a percutaneous short-term external heart assist device from MS–DRG 215 to MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively). According to the requestor, there are two distinct clinical populations within MS–DRG 215: High-risk Percutaneous Coronary Intervention (PCI) patients receiving short term ''intraoperative'' external heart assist systems where the device is only used intraoperatively and is removed at the conclusion of the procedure, and those patients in or at risk of cardiogenic shock requiring longer heart pump support and ICU stays. The requestor stated that cases in which short-term external heart assist systems are placed intraoperatively require fewer resources. The requestor suggested that moving the less resource intensive cases that report a procedure code that describes the intraoperative insertion of short-term external heart assist systems from MS–DRG 215 into MS–DRG 216, 217, and 218, will clinically align the two distinctly different patient populations, and consequently will address the potential decrease in the relative weight of MS–DRG 215.

The requestor stated it performed its own analysis of claims in MS–DRG 215 that involve the intraoperative insertion of a short-term external heart assist device (as identified by the presence of ICD–10–PCS codes 02HA3RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous approach) and 5A0221D (Assistance with cardiac output using impeller pump, continuous). The requestor stated that its analysis found that if procedures involving intraoperative placement of a short-term external heart assist device were moved into MS–DRGs 216, 217 and 218, it would result in an increase in the average costs and average lengths of stay for the cases that would remain to be assigned to MS–DRG 215.

As discussed in the proposed rule, during our review of this issue, we noted that when a patient is admitted and has an Impella® external heart assist device inserted two ICD–10–PCS codes are assigned: A code that describes the insertion of the device and code 5A0221D that describes assistance with an impeller pump. Therefore, our analysis included procedure code 02HA3RJ as identified by the requestor as well as similar procedure codes 02HA0RJ (Insertion of short-term external heart assist system into heart, intraoperative, open approach) and 02HA4RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous endoscopic approach) that also describe the intraoperative insertion of a short-term heart assist device, differing only in approach. Because the assistance with an Impella® is coded with ICD–10–PCS code 5A0221D whether the device is used only intraoperatively or in instances where the device is left in place at the conclusion of the procedure, we did not include this code in our analysis. We also noted that the requestor suggested that the cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device be moved to MS–DRGs 216, 217 and 218 but these MS–DRGs are defined by the performance of cardiac catheterization. Therefore, we expanded our analysis to also include MS–DRGs 219, 220 and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively).

We stated in the FY 2022 IPPS/LTCH PPS proposed rule that first, we examined claims data from the March 2020 update of the FY 2019 MedPAR file for MS–DRG 215 to identify cases reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ and a procedure code describing the performance of a cardiac catheterization. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	All cases	7,741	7.8	$68,234
	All intraoperative short-term external heart assist devices with cardiac catheterization	2,943	7.1	$60,449
	02HA0RJ with cardiac catheterization	23	8.9	$85,806
	02HA3RJ with cardiac catheterization	2,904	7.1	$60,227
	02HA4RJ with cardiac catheterization	16	6.4	$64,217

As shown in the table, we identified a total of 7,741 cases within MS–DRG 215 with an average length of stay of 7.8 days and average costs of $68,234. Of these 7,741 cases, there are 2,943 cases that include both a procedure code describing the intraoperative insertion of a short-term external heart assist device and a procedure code describing the performance of a cardiac catheterization with an average length of stay of 7.1 days and average costs of $60,449. Of these 2,943 cases, there are 23 cases reporting a procedure code describing the open intraoperative

insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization with an average length of stay of 8.9 days and average costs of $85,806. There are 2,904 cases reporting a procedure code describing a percutaneous intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization with an average length of stay of 7.1 days and average costs of $60,227. There are 16 cases reporting a procedure code describing a percutaneous endoscopic intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization approach with an average length of stay of 6.4 days and average costs of $64,217. The data analysis shows that for the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ with a procedure code describing the performance of a cardiac catheterization, generally, the average length of stay is shorter and the average costs are lower than the average length of stay and average costs (with the exception of the average costs and length of stay for the 23 cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization which are higher) compared to all cases in that MS–DRG.

In the proposed rule, we indicated that we also examined claims data from the March 2020 update of the FY 2019 MedPAR file for MS–DRGs 216, 217 and 218. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
216	5,603	16.7	$74,413
217	1,885	9.5	$47,159
218	210	6.6	$37,778

Because MS–DRG 215 is a base DRG and there is a three-way split within MS–DRGs 216, 217, and 218, we indicated that we also analyzed the cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization with MCC	1,886	9	$66,524
	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization with CC	778	4.1	$49,481
	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization without CC/MCC	278	2.5	$49,942

This data analysis shows the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ with a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC) have average costs generally more similar to the average costs in the FY 2019 MedPAR file for MS–DRGs 216, 217 and 218 respectively, while the average lengths of stay are shorter. While the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization ''with CC'' and ''without CC/MCC'' have higher average costs than the average costs of MS–DRGs 217 and 218, these costs are closer to the average costs of those MS–DRGs than they are to the average costs of MS–DRG 215. The average costs of the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization ''with MCC'' are lower than the average costs of both MS–DRGs 215 and 216.

Next, we examined claims data from the March 2020 update of the FY 2019 MedPAR file for MS–DRG 215 to identify cases reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	All cases	7,741	7.8	$68,234
	All intraoperative short-term external heart assist devices without cardiac catheterization	432	4.8	$53,607
	02HA0RJ without cardiac catheterization	8	8.8	$141,242
	02HA3RJ without cardiac catheterization	423	4.7	$51,964
	02HA4RJ without cardiac catheterization	1	2	$47,289

As shown in the table, of the 7,741 cases within MS–DRG 215, there are 432 cases that include a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 4.8 days and average costs of $53,607. Of these 432 cases, there are eight cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 8.8 days and average costs of $141,242. There are 423 cases reporting a procedure code describing a percutaneous intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 4.7 days and average costs of $51,964. There is one case reporting a procedure code describing a percutaneous endoscopic intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization approach with a length of stay of 2 days and costs of $47,289. We noted that the data analysis shows that for the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization, generally, the average length of stay is shorter and the average costs are lower than the average length of stay and average costs (with the exception of the average costs and length of stay for the eight cases describing the open intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization which are higher) compared to all cases in that MS–DRG.

We also examined claims data from the March 2020 update of the FY 2019 MedPAR file for MS–DRGs 219, 220 and 221. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
219	15,597	10.9	$57,845
220	15,074	6.5	$39,565
221	2,417	4.5	$33,560

Similarly, because MS–DRG 215 is a base DRG and there is a three-way split within MS–DRGs 219, 220 and 221, we stated that we also analyzed the cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization with MCC	205	7.3	$60,274
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization with CC	158	2.7	$46,745
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization without CC/MCC	68	1.4	$41,050

We indicated in the proposed rule that this data analysis shows the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC) have average costs generally more similar to the average costs in the FY 2019 MedPAR file for MS–DRGs 219, 220 and 221 respectively, while the average lengths of stay are shorter. While the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device, without a procedure code describing the performance of a cardiac catheterization ''with MCC'', ''with CC'' and ''without CC/MCC'' have higher average costs than the average costs MS–DRGs 219, 220 and 221, respectively, these costs are closer to the average costs of those MS–DRGs than they are to the average costs of MS–DRG 215.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for MS–DRG 215 to identify cases reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ with a procedure code describing the performance of a cardiac catheterization. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	All cases	6,275	7.9	$72,144
	All intraoperative short-term external heart assist devices with cardiac catheterization	2,395	6.8	$62,260
	02HA0RJ with cardiac catheterization	25	8.2	$85,954
	02HA3RJ with cardiac catheterization	2,360	6.8	$61,965
	02HA4RJ with cardiac catheterization	10	6.9	$72,564

As shown in the table, we identified a total of 6,275 cases within MS–DRG 215 with an average length of stay of 7.9 days and average costs of $72,144. Of these 6,275 cases, there are 2,395 cases that include both a procedure code describing the intraoperative insertion of a short-term external heart assist device and a procedure code describing the performance of a cardiac catheterization with an average length of stay of 6.8 days and average costs of $62,260. Of these 2,395 cases, there were 25 cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization with an average length of stay of 8.2 days and average costs of $85,954. There are 2,360 cases reporting a procedure code describing a percutaneous intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization with an average length of stay of 6.8 days and average costs of $61,965. There are 10 cases reporting a procedure code describing a percutaneous endoscopic intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization approach with an average length of stay of 6.9 days and average costs of $72,564. The data analysis shows that for the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or

02HA4RJ with a procedure code describing the performance of a cardiac catheterization, when examined collectively, the average length of stay is shorter (6.8 days versus 7.9 days) and the average costs are lower ($62,260 versus $72,144) than the average length of stay and average costs (of all cases in that MS–DRG). We noted there were some differences noted in cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization when examined by operative approach. For the 25 cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization, the average costs were higher ($85,954 versus $72,144) and average length of stay was slightly longer (8.2 days versus 7.9 days) when compared to all cases in that MS–DRG. For the 10 cases reporting a procedure code describing the percutaneous endoscopic intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization, the average costs were nearly equal ($72,564 versus $72,144) and average length of stay was shorter (6.9 days versus 7.9 days) when compared to all cases in that MS–DRG.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for MS–DRGs 216, 217 and 218. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
216	4,279	16.5	$79,786
217	1,310	9.4	$49,109
218	121	6.6	$43,504

Because MS–DRG 215 is a base DRG and there is a three-way split within MS–DRGs 216, 217, and 218, we also analyzed the cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization with MCC	1,522	8.7	$68,543
	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization with CC	632	3.8	$51,908
	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization without CC/MCC	241	2.5	$49,726

This data analysis shows the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ with a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC) have average costs generally more similar to the average costs in the FY 2020 MedPAR file for MS–DRGs 216, 217 and 218 respectively, while the average lengths of stay are shorter. While the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization ''with CC'' and ''without CC/MCC'' have higher average costs than the average costs of MS–DRGs 217 and 218, these costs are closer to the average costs of those MS–DRGs than they are to the average costs of MS–DRG 215. The average costs of the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization ''with MCC'' are lower than the average costs of both MS–DRGs 215 and 216.

Next, we examined claims data from the September 2020 update of the FY 2020 MedPAR file for MS–DRG 215 to identify cases reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	All cases	6,275	7.9	$72,144
	All intraoperative short-term external heart assist devices without cardiac catheterization	331	4.5	$52,181
	02HA0RJ without cardiac catheterization	8	8.9	$80,314
	02HA3RJ without cardiac catheterization	322	4.4	$51,569
	02HA4RJ without cardiac catheterization	1	2	$24,379

As shown in the table, of the 6,275 cases within MS–DRG 215, there are 331 cases that include a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 4.5 days and average costs of $52,181. Of these 331 cases, there are eight cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 8.9 days and average costs of $80,314. There are 332 cases reporting a procedure code describing a percutaneous intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 4.4 days and average costs of $51,569. There is one case reporting a procedure code describing a percutaneous endoscopic intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization approach with a length of stay of 2 days and costs of $24,379. The data analysis shows that for the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization, generally, the average length of stay is shorter and the average costs are lower than the average length of stay and average costs (with the exception of the average costs and length of stay for the eight cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization which are higher) compared to all cases in that MS–DRG.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for MS–DRGs 219, 220 and 221. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
219	11,863	10.9	$61,934
220	10,072	6.5	$41,800
221	1,440	4.2	$36,242

Similarly, because MS–DRG 215 is a base DRG and there is a three-way split within MS–DRGs 219, 220 and 221, we also analyzed the 331 cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization with MCC	161	6.5	$57,285
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization with CC	103	3	$47,996
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization without CC/MCC	67	1.7	$46,352

This data analysis shows the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC) have average costs generally more similar to the average costs in the FY 2020 MedPAR file for MS–DRGs 219, 220 and 221 respectively, while the average lengths of stay are shorter. While the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization ''with CC'' and ''without CC/MCC'' have higher average costs than the average costs of MS–DRGs 220 and 221, these costs are closer to the average costs of those MS–DRGs than they are to the average costs of MS–DRG 215. The average costs of the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization ''with MCC'' are lower than the average costs of both MS–DRGs 215 and 219.

We indicated in the proposed rule that our clinical advisors reviewed the clinical issues and the claims data and agreed that cases reporting a procedure code that describes the intraoperative insertion of a short-term external heart assist device are generally less resource intensive and are clinically distinct from other cases reporting procedure codes describing the insertion of other types of heart assist devices currently assigned to MS–DRG 215. Our clinical advisors stated that critically ill patients who are experiencing or at risk for cardiogenic shock from an emergent event such as heart attack or virus that impacts the functioning of the heart and requires longer heart pump support are different from those patients who require intraoperative support only. Patients receiving a short-term external heart assist device intraoperatively during coronary interventions often have an underlying disease pathology such as heart failure related to occluded coronary vessels that is broadly similar in kind to other patients also receiving these interventions without the need for an insertion of a short-term external heart assist device. In the post-operative period, these patients can recover and can be sufficiently rehabilitated prior to discharge. For these reasons, we indicated our clinical advisors supported reassigning ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device to MS–DRGs 216, 217, 218, 219, 220 and 221 in MDC 05. They stated this reassignment would improve clinical coherence in these MS–DRGs.

To compare and analyze the impact of our suggested modifications, we ran a simulation using the Version 38.1 ICD–10 MS–DRG GROUPER and the claims data from the March 2020 update of the FY 2019 MedPAR file. The following table reflects our simulation for ICD–10–PCS procedure codes 02HA0RJ, 02HA3RJ or 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device if they were moved to MS–DRGS 216, 217, 218, 219, 220 and 221.

MS-DRG		Number of Cases	Average Length of Stay	Average Cost
215	All Cases	7,741	7.8	$68,234
	without 02HA0RJ, 02HA3RJ or 02HA4RJ	4,798	8.2	$73,009
216	All Cases	5,603	16.7	$74,413
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	7,490	14.8	$72,424
217	All Cases	1,885	9.5	$47,159
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	2,663	7.9	$47,837
218	All Cases	210	6.6	$37,778
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	488	4.3	$44,708
219	All Cases	15,597	10.9	$57,845
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	17,484	10.7	$58,781
220	All Cases	15,074	6.5	$39,565
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	15,852	6.4	$40,052
221	All Cases	2,417	4.5	$33,560
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	2,695	4.3	$35,250

We stated in the proposed rule that we believe the resulting proposed MS–DRG assignments would be more clinically homogeneous, coherent and better reflect hospital resource use while at the same time addressing concerns related to the relative weight of MS–DRG 215. A review of this simulation shows that this distribution of ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device if moved to MS–DRGs 216, 217, 218, 219, 220 and 221, increases the average costs of the cases remaining in MS–DRG 215 by over $4,500, while generally having a more limited effect on the average costs of MS–DRGs 216, 217, 218, 219, 220 and 221.

We also ran a simulation using the Version 38.1 ICD–10 MS–DRG GROUPER and the claims data from the September 2020 update of the FY 2020 MedPAR file. The following table reflects our simulation for ICD–10–PCS procedure codes 02HA0RJ, 02HA3RJ or 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device if they were moved to MS–DRGS 216, 217, 218, 219, 220 and 221.

MS-DRG		Number of Cases	Average Length of Stay	Average Cost
215	All Cases	6,275	7.9	$72,144
	without 02HA0RJ, 02HA3RJ or 02HA4RJ	3,880	8.6	$78,245
216	All Cases	4,279	16.5	$79,786
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	5,801	14.5	$76,835
217	All Cases	1,310	9.4	$49,109
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	1,942	7.6	$50,020
218	All Cases	121	6.6	$43,504
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	362	3.8	$47,646
219	All Cases	11,863	10.9	$61,934
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	13,385	10.7	$62,685
220	All Cases	10,072	6.5	$41,800
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	10,704	6.3	$42,397
221	All Cases	1,440	4.2	$36,242
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	1,681	4.0	$38,175

As with our simulation based on the March 2020 update of the FY 2019 MedPAR file, we indicated we believe that this simulation supports that the resulting proposed MS–DRG assignments would be more clinically homogeneous, coherent and better reflect hospital resource use while at the same time addressing concerns related to the relative weight of MS–DRG 215. We noted that a review of this simulation shows that this distribution of ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device if moved to MS–DRGs 216, 217, 218, 219, 220 and 221, increases the average costs of the cases remaining in MS–DRG 215 by over $6,000, while generally having a more limited effect on the average costs of MS–DRGS 216, 217, 218, 219, 220 and 221.

Therefore, for FY 2022, we proposed to reassign ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ from MDC 05 in MS–DRG 215 to MS–DRGs 216, 217, 218, 219, 220 and 221 in MDC 05.

Comment: Commenters supported the proposal to reassign ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ from MDC 05 in MS–DRG 215. These commenters stated they appreciated CMS' attention, careful review and efforts to create more long-term stability for heart assist devices, a life-saving technology. Some commenters stated CMS' actions will create a more clinically balanced structure for hospital payments for patients needing short-term external heart assist device support. Commenters stated that this reassignment will better reflect hospital resource utilization creating a more clinically homogenous coherent structure for acute patients that require intraoperative support of a short-term external heart assist device. A commenter stated this reassignment would also result in a relative weight for MS–DRG 215 that more accurately reflects the resource utilization of the procedures within that MS–DRG, as well as stabilizing the relative weight for MS–DRG 215, which has fluctuated over the last few years. Another commenter acknowledged intraoperative cases require fewer hospital resources during their admission than all other cases in MS–DRG 215 and stated removing ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ describing intraoperative use from MS–DRG 215 maintains appropriate payment for longer term circulatory support, such as cardiogenic shock patients, who require more intensive resource use.

Response: We thank the commenters for their support.

Comment: Other commenters opposed CMS' proposal to reassign the short-term heart assist device ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ from MDC 05 in MS–DRG 215 to MS–DRGs 216, 217, 218, 219, 220 and 221 in MDC 05. Some commenters urged CMS to reconsider the proposal regarding short-term external heart assist devices and leave procedure codes 02HA0RJ, 02HA3RJ, and 02HA4RJ in MS–DRG 215 where they are currently assigned. These commenters noted patients requiring intraoperative short-term external heart assist devices tend to be more severely ill and stated the proposal does not fully consider the complexity of care required for these patients and the associated resource utilization, in terms of the need for additional length of stay and monitoring. A commenter stated short-term external heart assist systems, require high resources consumption evidenced by critical care management, expensive drugs and tests; and specialized clinical staff such as: Physicians, nursing, perfusionists, etc. Another commenter stated they believe there may be hospital-specific differences with some facilities performing the diagnostic cardiac catheterizations as outpatient services prior to the inpatient admission for the other cardiothoracic procedures. A commenter expressed concern about the impact this change would have related to the increased use of the external heart assist devices and resources required to insert the device, including the cost of the device. This commenter stated an estimated 50% of the cases at their facility involving a short-term heart assist device would fall into a CC or NonCC category under the proposed MS–DRG change in spite of the fact the patients who require this device are at higher risk, which would mean that approximately 50% of their Medicare payment would be allocated to the cost

of the device itself. This commenter stated that an even greater negative financial impact may be recognized as there has been an increase in the use of Impella® devices due to higher incidence of advanced ischemic cardiomyopathy because of the COVID–19 pandemic and delays in treatment.

Another commenter requested that CMS consider re-evaluation once the MedPAR data are normalized from the pandemic to consider structure revisions for these MS–DRGs. This commenter noted that there is a proposed relative weight reduction from 11.1579 to 10.5614 for MS- DRG 215 even though CMS proposed to move the intraoperative short-term heart assist devices from this MS–DRG. This commenter stated this reduction does not seem appropriate especially if the proposed MS–DRG changes are finalized.

Response: We thank the commenters for their feedback. Our clinical advisors have reviewed these concerns regarding the proposed reassignment and continue to state the resulting MS–DRG assignments, as proposed, would be more clinically homogeneous, coherent and better reflect hospital resource use because cases reporting a procedure code that describes the intraoperative insertion of a short-term external heart assist device are generally less resource intensive and are clinically distinct from other cases reporting procedure codes describing the insertion of other types of heart assist devices currently assigned to MS–DRG 215. Our clinical advisors acknowledge that while the need to have a short term heart assist device inserted can reflect on the severity of illness of the patient being treated, critically ill patients who are experiencing or at risk for cardiogenic shock from an emergent event such as heart attack or virus that impacts the functioning of the heart and require longer heart pump support and ICU stays are different from those patients who require intraoperative support only where the device is removed at the conclusion of the procedure. As additional claims data become available, we will continue to analyze the clinical nature of each of the procedures describing the insertion of short-term heart assist devices and their MS–DRG assignments to further improve the overall accuracy of the IPPS payments in future rulemaking.

Comment: While indicating their support of CMS' proposal, some commenters urged CMS to refrain from moving cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device into MS–DRG 219, 220, and 221. These commenters stated the cases should be assigned to MS–DRGs 216, 217 and 218 only, based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC). A few commenters stated that CMS should refrain from moving cases into MS–DRG 219, 220, or 221 because the claim volume of cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing a cardiac catherization is under five hundred and intracardiac heart assist devices, such as Impella® devices require the use of diagnostic catheters, fluoroscopy, and hemodynamic monitoring during use, all resulting in higher costs. Considering the types of procedures that utilize short term circulatory support and the techniques used by these circulatory support devices, these commenters stated cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device are comparable to those mapping to MS–DRG 216, 217 and 218, even when a cardiac catherization procedure is not performed. Other commenters asserted there are known coding and documentation issues seen with this complex therapy, without providing examples of these issues, and stated that reassigning ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ to MS–DRGs 219, 220, and 221, described as ''without cardiac catheterization'' may lead to coding errors since the vast majority of these procedures necessitate a cardiac catheterization.

Response: We note that the requestor originally suggested that the cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device be moved to MS–DRGs 216, 217 and 218 but because these MS–DRGs are defined by the performance of cardiac catheterization, we specifically expanded our analysis to also include MS–DRGs 219, 220 and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively). We do not believe it would be appropriate to assign all cases to the ''with cardiac catheterization'' MS–DRGs because the claims data would not reflect the additional resources associated with the performance of a cardiac catheterization in cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device.

As presented in the proposed rule and in this final rule, the data analysis performed show in both in the FY 2019 MedPAR file and the FY 2020 MedPAR file, the average length of stay is shorter and the average costs are lower in cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without the performance of a cardiac catheterization when compared to cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with the performance of a cardiac catheterization when analyzed for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

Our clinical advisors believe that continued monitoring of the data and further analysis is needed prior to proposing any additional modifications to the MS–DRG assignment of cases reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization. Our clinical advisors believe maintaining the distinction between the performance of or lack of a cardiac catherization procedure is important in these subsets of cases as we continue to examine the volume and length of stay as well as considering a variety of factors pertaining to resource consumption and clinical characteristics that might account for differences in resource use before determining if additional modifications to the assignment of these procedure codes are warranted.

In response to the suggestion that we refrain from moving cases into MS–DRG 219, 220, or 221 because claim volume of cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing a cardiac catherization is low, we do not believe moving this subset of cases into an incoherent grouping simply because the case volume is low is in keeping with our goal to maintain clinically coherent groups that also more accurately stratify Medicare patients with varying levels of severity.

Similarly, in response to the comments asserting that there are known coding and documentation issues seen with this complex therapy and that reassigning ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ to MS–DRGs 219, 220, and 221, described as ''without cardiac catheterization'' may lead to coding errors since the vast majority of these procedures necessitate

a cardiac catheterization, we again do not believe moving cases into an MS–DRG because of the need for improved provider documentation or any additional coder instruction is in keeping with our goal to maintain clinically coherent groups that also more accurately stratify Medicare patients with varying levels of severity. We acknowledge that accurate coding of external heart assist devices has been the subject of confusion in the past, and we will continue to monitor the claims data for these procedures. As one of the four Cooperating Parties, we also will continue to collaborate with the American Hospital Association to provide guidance for coding external heart assist devices through the Coding Clinic for ICD–10–CM/PCS publication and to review the ICD–10–PCS guidelines to determine where further clarifications may be made.

Therefore, after consideration of the public comments we received, and for reasons stated previously, we are finalizing our proposal to reassign ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ from MDC 05 in MS–DRG 215 to MS–DRGs 216, 217, 218, 219, 220 and 221 in MDC 05, without modification, effective October 1, 2021.

b. Type II Myocardial Infarction

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25115 through 25116), we discussed a request we received to review the MS–DRG assignment of ICD–10–CM diagnosis code I21.A1 (Myocardial infarction type 2). The requestor stated that when a type 2 myocardial infarction is documented, per coding guidelines, it is to be coded as a secondary diagnosis since it is due to an underlying cause. This requestor also noted that when a type 2 myocardial infarction is coded with a principal diagnosis in MDC 05 (Diseases and Disorders of the Circulatory System), the GROUPER logic assigns MS–DRGs 280 through 282 (Acute Myocardial Infarction, Discharged Alive with MCC, with CC, and without CC/MCC, respectively). The requestor questioned if this GROUPER logic was correct or if the logic should be changed so that a type 2 myocardial infarction, coded as a secondary diagnosis, does not result in the assignment of a MS–DRG that describes an acute myocardial infarction.

As discussed in the proposed rule, to begin our analysis, we reviewed the GROUPER logic. We noted that the requestor is correct that when diagnosis code I21.A1 is reported as a secondary diagnosis in combination with a principal diagnosis in MDC 05, the case currently groups to medical MS–DRGs 280 through 282 in the absence of a surgical procedure, when the patient is discharged alive. We also noted that if the patient expires, GROUPER logic instead will assign MS–DRGs 283 through 285 (Acute Myocardial Infarction, Expired with MCC, with CC, and without CC/MCC, respectively) when diagnosis code I21.A1 is reported as a secondary diagnosis in combination with a principal diagnosis in MDC 05.

According to the Universal Definition of Myocardial Infarction (MI), developed by a global task force that included the European Society of Cardiology, the American College of Cardiology, the American Heart Association and the World Heart Federation (WHF), the diagnosis of MI requires the rise and/or fall of cardiac biomarkers with clinical evidence of ischemia in which there is evidence of myocardial injury or necrosis, defined by symptoms, electrocardiographic (ECG) changes, or new regional wall motion abnormalities. Since 2007, this definition further classifies myocardial infarctions into five distinct subtypes. While a type 1 MI is defined as a MI due to an acute coronary syndrome, type 2 MI is defined as a mismatch in myocardial oxygen supply and demand due to other causes such as coronary dissection, vasospasm, emboli, or hypotension that is not attributed to unstable coronary artery disease (CAD).

We indicated in the proposed rule that our clinical advisors reviewed this issue and did not recommend changing the current MS–DRG assignment of ICD–10–CM diagnosis code I21.A1. As noted by the requestor, the ICD–10–CM Official Guidelines for Coding and Reporting state ''Type 2 myocardial infarction, (myocardial infarction due to demand ischemia or secondary to ischemic imbalance) is assigned to code I21.A1, Myocardial infarction type 2 with a code for the underlying cause coded first.'' We indicated our clinical advisors believed that cases reporting diagnosis code I21.A1 as a secondary diagnosis are associated with a severity of illness on par with cases reporting a principal diagnosis of another type myocardial infarction. They stated the diagnosis of myocardial infarction describes myocardial cell death due to inadequate oxygen supply to the myocardium for a prolonged period, regardless of the subtype. Our clinical advisors further stated, for clinical consistency, it is more appropriate to maintain the current assignment of ICD–10–CM diagnosis code I21.A1 with the other codes that describe myocardial infarction. Therefore, we did not propose to reassign diagnosis code I21.A1 from MS–DRGs 280 through 285.

As discussed in the proposed rule, during our review of this issue we also noted that code I21.A1 (Myocardial infarction type 2) is currently one of the listed principal diagnoses in the GROUPER logic for MS–DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or Shock with and without MCC, respectively). However, code I21.A1 is not currently recognized in these same MS–DRGs when coded as a secondary diagnosis. As a result, when coded as a secondary diagnosis in combination with a principal diagnosis in MDC 05, MS–DRGs 224 and 225 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF, or Shock with and without MCC, respectively) are instead assigned when reported with a listed procedure code. We referred the reader to the ICD–10 MS–DRG Definitions Manual Version 38.1, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 222, 223, 224, and 225.

Acknowledging that coding guidelines instruct to code I21.A1 after the diagnosis code that describes the underlying cause, we indicated our clinical advisors recommended adding special logic in MS–DRGs 222 and 223 to have code I21.A1 also qualify when coded as a secondary diagnosis in combination with a principal diagnosis in MDC 05 since these diagnosis code combinations also describe acute myocardial infarctions.

As a result, we proposed modifications to the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with a listed procedure code for clinical consistency with the other MS–DRGs describing acute myocardial infarction.

A diagnosis code may define the logic for a specific MS–DRG assignment in three different ways. The diagnosis code may be listed as principal or as any one of the secondary diagnoses, as a secondary diagnosis, or only as a secondary diagnosis as noted in more detail in the proposed rule and this final rule.

- Principal or secondary diagnoses. Indicates that a specific set of diagnoses are used in the definition of the MS–DRG. The diagnoses may be listed as principal or as any one of the secondary diagnoses. A special case of this condition is MS–DRG 008 in which two

diagnoses (for example, renal and diabetic) must both be present somewhere in the list of diagnoses in order to be assigned to MS–DRG 008.

• Secondary diagnoses. Indicates that a specific set of secondary diagnoses are used in the definition of the MS–DRG. For example, a secondary diagnosis of acute leukemia with chemotherapy is used to define MS–DRG 839.

• Only secondary diagnoses. Indicates that in order to be assigned to the specified MS–DRG no secondary diagnoses other than those in the specified list may appear on the patient's record. For example, in order to be assigned to MS–DRG 795, only secondary diagnoses from the specified list may appear on the patient's record.

We noted in the proposed rule that whenever there is a secondary diagnosis component to the MS–DRG logic, the diagnosis code can either be used in the logic for assignment to the MS–DRG or to act as a CC/MCC. For this specific scenario, we proposed that code I21.A1, as a secondary diagnosis, be used in the definition of the logic for assignment to MS–DRGs 222 and 223, similar to the example described previously, where a secondary diagnosis of acute leukemia with chemotherapy is used to define MS–DRG 839, and therefore will not act as an MCC in these MS–DRGs.

In summary, for FY 2022, we proposed to maintain the current structure of MS–DRGs 280 through 285. We proposed to modify the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures.

Comment: A commenter agreed with CMS' proposed modifications to the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS–DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or Shock with and without MCC, respectively) when reported with qualifying procedures. This commenter stated they agreed that coding rules stipulate that diagnosis code I21.A1 must be reported as a secondary diagnosis.

Response: We appreciate the commenters' support.

Comment: Other commenters expressed concern with CMS' proposal. A commenter stated that they believed it is inappropriate to include cases with diagnosis code I21.A1 in the MS–DRGs that describe an acute myocardial infarction (MS–DRGs 280 through 285). The commenter expressed concern that if cases reporting diagnosis code I21.A1 are assigned to the MS–DRGs that describe an acute myocardial infarction, this would disrupt the resource accuracy of these MS–DRGs. They stated from a clinical perspective, the pattern of care for patients with type 2 MI may vary considerably compared to the treatment of patients with other types of myocardial infarctions, namely Type 1 STEMI and Type 1 NSTEMI. This commenter however, agreed with the proposal to modify the GROUPER logic to allow cases reporting diagnosis code I21.A1 as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures and stated this portion of the proposal aligns with the intended use of type 2 MI and creates clinical consistency in MS–DRGs. The commenter also stated while it is inappropriate for diagnosis code I21.A1 to be classified as the diagnosis driving MS–DRG assignment, type 2 MI should be classified as a major complication or comorbidity (MCC) because patients with type 2 MI face an increased mortality risk. Another commenter stated the proposed rule did not provide rationale as to why code I21.A1 would not act as an MCC under the proposal to revise the GROUPER logic to allow cases reporting diagnosis code I21.A1 as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures. This commenter requested that data analysis be provided on the instances when this code would not act as an MCC.

Response: We appreciate the commenters' feedback. We note to that the GROUPER logic assignment for each diagnosis code as a principal diagnosis is for grouping purposes only. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41217) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58519), because the diagnoses are codes listed under the heading of ''Principal Diagnosis'' in the ICD–10 MS–DRG Definitions Manual, it may appear to indicate that these codes are to be reported as a principal diagnosis for assignment to these MS–DRGs. However, the Definitions Manual display of the GROUPER logic assignment for each diagnosis code does not correspond to coding guidelines for reporting the principal diagnosis. The MS–DRG logic must specifically require a condition to group based on whether it is reported as a principal diagnosis or a secondary diagnosis, and consider any procedures that are reported, in addition to consideration of the patient's age, sex and discharge status in order to affect the MS–DRG assignment. In other words, cases will group according to the GROUPER logic, regardless of any coding guidelines or coverage policies. It is the Medicare Code Editor (MCE) and other payer-specific edits that identify inconsistencies in the coding guidelines or coverage policies. These data integrity edits address issues such as data validity, coding rules, and coverage policies. Since the inception of the IPPS, the data editing function has been a separate and independent step in the process of determining a DRG assignment. The separation of the MS–DRG grouping and data editing functions allows the MS–DRG GROUPER to remain stable even though coding rules and coverage policies may change during the fiscal year.

In response to the commenter that stated that if type 2 MI cases are assigned to the MS–DRGs that describe an acute myocardial infarction, this would disrupt the resource accuracy of these MS–DRGs, while at the same time agreeing with the proposal to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures, we are unclear of the commenters' rationale for these conflicting statements. Specifically, because MS–DRGs 222 and 223 also describe an acute myocardial infarction, it is unclear why the commenter indicates a type 2 MI should only be considered an MI in this instance.

In response to the commenter that stated that CMS did not provide rationale as to why code I21.A1 would not act as an MCC under the proposal to revise the GROUPER logic in MS–DRGs 222 and 223 and in response to their request that data analysis be provided on the instances when this code would not act as an MCC, as we indicated in the proposed rule, whenever there is a secondary diagnosis component to the MS–DRG logic, the diagnosis code can either be used in the logic for assignment to the MS–DRG or to act as a CC/MCC. It is not a question of data analysis. Although I21.A1 is designated as an MCC when reported as a secondary diagnosis, if code I21.A1, as a secondary diagnosis, is being used in the definition of the logic for assignment to MS–DRGs 222 and 223, it cannot act as an MCC in these MS–DRGs. Therefore, outside of MS–DRGs 222, 223, 280, 281, 282, 283, 284 and 285, diagnosis code I21.A1 will continue to act as an MCC when reported as a secondary diagnosis in Version 39.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current structure of MS–DRGs 280 through 285, without modification, for

FY 2022. We are also finalizing our proposal, without modification, to modify the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures, effective October 1, 2021.

c. Viral Cardiomyopathy

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25116 through 25117), we discussed three separate but related requests that we received to add ICD–10–CM diagnosis code B33.24 (Viral cardiomyopathy) to the list of principal diagnoses for MS–DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively) in MDC 05. The requestors noted that a discontinuity exists in the current MDC assignment of diagnosis codes in ICD–10–CM subcategory B33.2. The list of the five ICD–10–CM diagnosis codes in subcategory B33.2, as well as their current MDC assignments, is found in the following table.

ICD-10-CM Code	Code Description	MDC
B33.20	Viral carditis, unspecified	05
B33.21	Viral endocarditis	05
B33.22	Viral myocarditis	05
B33.23	Viral pericarditis	05
B33.24	Viral cardiomyopathy	18

A requestor noted ICD–10–CM codes B33.20, B33.21, B33.22, and B33.23 are assigned to MDC 05 (Diseases and Disorders of the Circulatory System), while code B33.24 is assigned to MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites). The requestor stated that the placement of ICD–10–CM diagnosis code B33.24 within subcategory B33.2 is clinically appropriate, as all the diagnoses within this subcategory share a common etiology, involve the heart and supporting structures, and require the same intensity of hospital care. However, the assignment of code B33.24 to a different MDC is clinically incongruous with the placement of the other codes in the subcategory. According to the requestor, all of the conditions share similar etiology, anatomic location, and needs for care, therefore the five codes should all be assigned to MDC 05. This requestor also stated that reassigning code B33.24 to MDC 05 would ensure both clinical continuity and coding consistency within the B33.2 subcategory. Another requestor stated MDC 05 surgical MS–DRGs should be assigned when procedures such as cardiac catheterization or coronary angioplasty are performed for a principal diagnosis of viral cardiomyopathy.

In the proposed rule, we indicated that to begin our analysis, we reviewed the GROUPER logic. We noted that currently, cases reporting ICD–10–CM diagnosis code B33.24 as a principal diagnosis group to medical MS–DRGs 865 and 866 (Viral Illness with and without MCC, respectively) in MDC 18 in the absence of a surgical procedure. We indicated our clinical advisors reviewed this issue and noted viral cardiac infections may present as endocarditis (inflammation of the heart's inner lining), myocarditis (inflammation of the middle layer of the heart), pericarditis (inflammation of the pericardium), or cardiomyopathy (disease of the heart muscle). The infection usually begins somewhere other than the heart, often in the nose, lungs, or stomach. As the infection progresses, and the microbe multiplies and gets into the bloodstream, it can infiltrate the heart muscle. The growth and replication of viruses inside the heart can endanger the heart by destroying heart cells. The management of viral cardiomyopathy is similar to the management of other viral cardiac infections and can include bed rest, control of pain with non-steroidal anti-inflammatory agents and anti-microbial therapy to avoid permanent myocardial damage, cardiomegaly, and/or congestive cardiac failure.

We indicated our clinical advisors agreed that the diagnosis of viral cardiomyopathy is clinically related to the other diagnoses in ICD–10–CM subcategory B33.2. We stated that they believed it is clinically appropriate for all five diagnoses in subcategory B33.2 to group to MDC 05 (Diseases and Disorders of the Circulatory System) as these conditions describe circulatory system conditions and complications and that this modification will improve clinical coherence. Therefore, we proposed to reassign ICD–10–CM diagnosis code B33.24 from MDC 18 in MS DRGs 865 and 866 (Viral Illness with and without MCC, respectively) to MDC 05 in MS DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively). We stated in the proposed rule that, under this proposal, cases reporting procedure codes from MDC 05 in conjunction with principal diagnosis B33.24, would group to MS–DRGs in MDC 05.

Comment: Commenters agreed with CMS' proposal to reassign ICD–10–CM diagnosis code B33.24 (Viral cardiomyopathy) from MDC 18 in MS DRGs 865 and 866 (Viral Illness with and without MCC, respectively) to MDC 05 in MS–DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively). Commenters stated this change will improve clinical coherence since viral cardiomyopathy is closely related to the other viral heart diseases in subcategory B33.2 that are already assigned to MDC 05.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–CM diagnosis code B33.24 from MDC 18 in MS DRGs 865 and 866 (Viral Illness with and without MCC, respectively) to MDC 05 in MS DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively), without modification, effective October 1, 2021.

d. Left Atrial Appendage Closure (LAAC)

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58471 through 58477), we identified nine ICD–10–PCS procedure codes that describe Left Atrial Appendage Closure (LAAC) procedures and noted their corresponding MS–DRG assignments in the ICD–10 MS–DRGs Version 37 as listed in the following table.

ICD-10-PCS Code	MS-DRG	Description
02L70CK	250-251	Occlusion of left atrial appendage with extraluminal device, open approach
02L70DK	250-251	Occlusion of left atrial appendage with intraluminal device, open approach
02L70ZK	250-251	Occlusion of left atrial appendage, open approach
02L73CK	273-274	Occlusion of left atrial appendage with extraluminal device, percutaneous approach
02L73DK	273-274	Occlusion of left atrial Appendage with intraluminal device, percutaneous approach
02L73ZK	273-274	Occlusion of left atrial appendage, percutaneous approach
02L74CK	273-274	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic approach
02L74DK	273-274	Occlusion of left atrial appendage with intraluminal device, percutaneous endoscopic approach
02L74ZK	273-274	Occlusion of left atrial appendage, percutaneous endoscopic approach

As discussed in the FY 2021 IPPS/LTCH PPS final rule, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting LAAC procedures with an open approach in MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with and without MCC, respectively). Our analysis showed that the cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 had higher average costs and longer average length of stay compared to all cases in MS–DRGs 250 and 251. We also stated our clinical advisors believed that ICD–10–PCS codes 02L70CK, 02L70DK, and 02L70ZK that describe a LAAC procedure with an open approach were more suitably grouped to MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectfully). Therefore, we finalized our proposal to reassign ICD–10–PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 to MS–DRGs 273 and 274. We also finalized a revision to the titles for MS–DRG 273 and 274 to Percutaneous and Other Intracardiac Procedures with and without MCC, respectively to reflect this reassignment for FY 2021.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25117 through 25118), we discussed a request we received to again review the MS–DRG assignment of cases involving LAAC procedures with an open approach in response to this final policy. The requestor disagreed with CMS' FY 2021 IPPS/LTCH PPS final rule decision to move the three procedure codes describing the open occlusion of left atrial appendage to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively). The requestor stated they believe that MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively), would more appropriately correspond with the open procedural resources and longer length of stay expected with open heart procedures.

We indicated in the proposed rule that our clinical advisors reviewed this request and continued to support the reassignment of ICD–10–PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 to MS–DRGs 273 and 274 because it allows all LAAC procedures to be grouped together under the same MS–DRGs and improves clinical coherence. Our clinical advisors stated open LAAC procedures are primarily performed in the absence of another O.R. procedure and generally are not performed with a more intensive open chest procedure. When performed as standalone procedures, open LAAC procedures share similar factors such as complexity and resource utilization with all other LAAC procedures. We noted that our clinical advisors continued to state our FY 2021 final policy results in MS–DRG assignments that are more clinically homogeneous and better reflect hospital resource use. Therefore, we proposed to maintain the assignment of codes 02L70CK, 02L70DK, and 02L70ZK that describe the open occlusion of the left atrial appendage in MS–DRGs 273 and 274.

Comment: A commenter expressed concern and requested that CMS reconsider its proposal to continue the assignment of the open LAAC procedure codes to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively) and instead assign these procedures to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively). This commenter acknowledged in response to the FY 2021 proposed rule, they supported CMS' proposal to reassign the open approach left atrial appendage procedure codes from MS–DRGs 250 and 251 to MS–DRGS 273 and 274 at that time. However, the commenter stated that because CMS did not provide a detailed analysis of the claims data for the average length of stay and average costs related to the cases reporting procedure codes describing the open occlusion of left atrial appendage in the FY 2022 proposed rule, it reviewed the data analysis as presented in the FY 2021 IPPS/LTCH PPS rule and compared it to the data analysis in Section II.D.5.d of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25118 through 25121) which was presented as part of the discussion of a two-part request to review the MS–DRG assignments for cases involving surgical ablation procedures for atrial fibrillation. The commenter stated based on their own analysis, it appeared the average length of stay and average costs of open occlusion of left atrial appendage procedures would be more clinically aligned with MS–DRGs 228 and 229.

Response: We appreciate the commenter's feedback. We note that the analysis discussed in FY 2021 rulemaking was based on the examination of claims data from the September 2019 update of the FY 2019 MedPAR file, while discussions in Section II. D. of the FY 2022 proposed rule are based on the examination of claims data from the March 2020 update of the FY 2019 MedPAR file, as well as the September 2020 update of the FY 2020 MedPAR file.

We display in the following tables claims analysis using claims data from the March 2020 update of the FY 2019 MedPAR file, as well as the September 2020 update of the FY 2020 MedPAR file. We examined claims data from the March 2020 update of the FY 2019 MedPAR file for all cases in MS–DRGs 273 and 274 and compared the results to cases with a procedure code describing an open LAAC procedure.

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MS-DRGs 273 and 274 - LAAC Procedures with Open Approach				
MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
273	All Cases	7,557	6.1	$28,356
	LAAC procedures with open approach	29	7.6	$52,365
274	All Cases	26,595	2	$24,295
	LAAC procedures with open approach	89	3.5	$25,185

In MS–DRG 273, we found a total of 7,557 cases with an average length of stay of 6.1 days and average costs of $28,356. Of those 7,557 cases, there were 29 cases reporting a LAAC procedure with an open approach, with an average length of stay of 7.6 days and average costs of $52,365. In MS–DRG 274, we found a total of 26,595 cases with an average length of stay of 2 days and average costs of $24,295. Of those 26,595 cases, there were 89 cases reporting a LAAC procedure with an open approach, with an average length of stay of 3.5 days and average costs of $25,185. The analysis shows that the cases reporting a LAAC procedure with an open approach in MS–DRGs 273 and 274 have higher average costs compared to all cases in MS–DRGs 273 and 274 ($52,365 versus $28,356 and $25,185 versus $24,295, respectively).

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for all cases in MS–DRGs 273 and 274 and compared the results to cases with a procedure code describing an open LAAC procedure.

MS-DRGs 273 and 274 - LAAC Procedures with Open Approach				
MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
273	All Cases	6,542	6.1	$30,671
	LAAC procedures with open approach	19	8.3	$47,421
274	All Cases	23,125	1.9	$25,880
	LAAC procedures with open approach	55	3.1	$20,995

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In MS–DRG 273, we found a total of 6,542 cases with an average length of stay of 6.1 days and average costs of $30,671. Of those 6,542 cases, there were 19 cases reporting a LAAC procedure with an open approach, with an average length of stay of 8.3 days and average costs of $47,421. In MS–DRG 274, we found a total of 23,125 cases with an average length of stay of 1.9 days and average costs of $25,880. Of those 23,125 cases, there were 55 cases reporting a LAAC procedure with an open approach, with an average length of stay of 3.1 days and average costs of $20,995. The analysis shows that the cases reporting a LAAC procedure with an open approach in MS–DRG 273 have higher average costs compared to all cases in MS–DRG 273 ($47,421 versus $30,671) while the cases reporting a LAAC procedure with an open approach in MS–DRG 274 have lower average costs compared to all cases in MS–DRG 274 ($20,995 versus $25,880).

While we recognize the average costs of the small number of cases reporting LAAC procedures with an open approach generally have average costs greater than the average costs of the cases in MS–DRGs 273 and 274 overall, our clinical advisors continue to support the reassignment of the open occlusion of left atrial appendage procedures, which was finalized in FY 2021 rulemaking. The MS–DRG system is a system of averages, and it is expected that across the diagnostic related groups that within certain groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs.

Our clinical advisors reviewed this issue and stated they do not believe that assigning procedure codes describing an open LAAC procedure to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) will improve clinical coherence, as this surgical class is not as precisely defined from a clinical perspective. MS–DRGs 228 and 229 are an example of the surgical MS–DRGs that are found within each MDC that include 'other' procedures intended to encompass procedures that, while not directly related to the MDC, can and do occur with principal diagnoses in that MDC with sufficient frequency.

Our clinical advisors note that, as stated in the ICD–10 MS–DRG Definitions Manual, ''In each MDC there is usually a medical and a surgical class referred to as ''other medical diseases'' and ''other surgical procedures,'' respectively. The ''other'' medical and surgical classes are not as precisely

defined from a clinical perspective. The other classes would include diagnoses or procedures which were infrequently encountered or not well defined clinically''. The ICD–10 MS–DRG Definitions Manual also states ''The ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC.''

Our clinical advisors continue to state that when performed as standalone procedures, open LAAC procedures share similar factors such as complexity and resource utilization with all other LAAC procedures. Moreover, our clinical advisors continue to support the FY 2021 reassignment of the open occlusion of left atrial appendage procedures because it allows all LAAC procedures to be grouped together under the same MS–DRGs and improves clinical coherence. After consideration of the public comments we received, and for the reasons stated previously, we are finalizing our proposal to maintain the assignment of codes 02L70CK, 02L70DK, and 02L70ZK that describe the open occlusion of the left atrial appendage in MS–DRGs 273 and 274, without modification, for FY 2022.

e. Surgical Ablation

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25118 through 25121), we discussed a two-part request we received to review the MS–DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation. Atrial fibrillation (AF) is an irregular and often rapid heart rate that occurs when the two upper chambers of the heart experience chaotic electrical signals. AF presents as either paroxysmal (lasting <7 days), persistent (lasting >7 day, but less than 1 year), or long standing persistent (chronic) (lasting >1 year) based on time duration and can increase the risk for stroke, heart failure, and mortality. Management of AF has two primary goals: Optimizing cardiac output through rhythm or rate control, and decreasing the risk of cerebral and systemic thromboembolism. Patients that worsen in symptomology or fail to respond to pharmacological treatment or other interventions may be referred for surgical ablation to treat their AF. Surgical ablation is a procedure that works by burning or freezing tissue on the inside of the heart to disrupt faulty electrical signals causing the arrhythmia, which can help the heart maintain a normal heart rhythm.

As discussed in the proposed rule, the first part of this request was to create a new classification of surgical ablation MS–DRGs to better accommodate the costs of open concomitant surgical ablations. According to the requestor, patients undergoing surgical ablation are treated under two potential scenarios: (1) Open concomitant (combination) surgical ablation, meaning open surgical ablation performed during another open-heart surgical procedure such as mitral valve repair or replacement (MVR), aortic valve repair or replacement (AVR), or coronary artery bypass grafting (CABG) and (2) minimally invasive, percutaneous endoscopic, standalone surgical ablation as the sole therapeutic procedure performed. According to the requestor, open concomitant surgical ablation is an efficient procedure, as it allows treatment of AF and another clinical pathology in one procedure thereby decreasing the risk of future readmits, need for future repeat catheter ablation procedures, and patient mortality.

The requestor identified the following potential procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure.

- Open CABG + open surgical ablation
- Open MVR + open surgical ablation
- Open AVR + open surgical ablation
- Open MVR + open AVR + open surgical ablation
- Open MVR + open CABG + open surgical ablation
- Open MVR + open AVR + open CABG + open surgical ablation
- Open AVR + open CABG + open surgical ablation

The requestor performed their own analysis of these procedure code combinations and stated that it found the average costs for open concomitant surgical ablation procedures were consistently higher compared to the average costs within their respective MS–DRGs, which could limit beneficiary access to these procedures.

The requestor suggested that the following four MS–DRGs be created to address the differences in average costs and average lengths of stay it found in its data analysis:

- Suggested New MS–DRG XXX—Open Surgical Ablation with or without Other Cardiothoracic Procedure with Cardiac Catheterization with MCC;
- Suggested New MS–DRG XXX—Open Surgical Ablation with or without Other Cardiothoracic Procedure with Cardiac Catheterization without MCC;
- Suggested New MS–DRG XXX—Open Surgical Ablation with or without Other Cardiothoracic Procedure without Cardiac Catheterization with MCC; and
- Suggested New MS–DRG XXX—Open Surgical Ablation with or without Other Cardiothoracic Procedure without Cardiac Catheterization without MCC.

In response to this request, we identified nine ICD–10–PCS codes that describe open surgical ablation. These codes and their corresponding MDC and MS–DRG assignments are listed in the following table.

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ICD-10-PCS Code	MDC	MS-DRG	Description
02540ZZ	05	228-229	Destruction of coronary vein, open approach
02550ZZ	05	228-229	Destruction of atrial septum, open approach
02560ZZ	05	228-229	Destruction of right atrium, open approach
02570ZK	05	250-251	Destruction of left atrial appendage, open approach
02570ZZ	05	228-229	Destruction of left atrium, open approach
02580ZZ	05	228-229	Destruction of conduction mechanism, open approach
02590ZZ	05	228-229	Destruction of chordae tendineae, open approach
025S0ZZ	04 05	163-165 270-272	Destruction of right pulmonary vein, open approach
025T0ZZ	04 05	163-165 270-272	Destruction of left pulmonary vein, open approach

We stated in the proposed rule that the ICD–10 MS–DRGs Definitions Manual Version 38.1, for open concomitant surgical ablation procedures, the GROUPER logic assigns MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) in most instances because MS–DRGs 228 and 229 are high in the surgical hierarchy GROUPER logic of MDC 05 (Diseases and Disorders of the Circulatory System). We would like to correct the statement in the proposed rule that, in ICD–10 MS–DRGs Definitions Manual Version 38.1, for open concomitant surgical ablation procedures, the GROUPER logic assigns MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) in most instances. We list in the following table the open concomitant surgical ablation procedure code combinations and their corresponding MS–DRG assignments in the ICD–10 MS–DRGs Definitions Manual Version 38.1.

Open Concomitant Surgical Ablation Procedure Code Combinations		
	MS-DRG	**Description**
Open CABG + Open Ablation	228-229	Other Cardiothoracic Procedures with and without MCC
Open CABG + Open MVR + Open Ablation	216-221	Cardiac Valve and Other Major Cardiothoracic Procedures with or without Cardiac Catheterization with MCC, with CC, and without CC/MCC
Open CABG + Open AVR + Open Ablation	216-221	Cardiac Valve and Other Major Cardiothoracic Procedures with or without Cardiac Catheterization with MCC, with CC, and without CC/MCC
Open CABG + Open MVR + Open AVR + Open Ablation	216-221	Cardiac Valve and Other Major Cardiothoracic Procedures with or without Cardiac Catheterization with MCC, with CC, and without CC/MCC
Open MVR + Open Ablation	216-221	Cardiac Valve and Other Major Cardiothoracic Procedures with or without Cardiac Catheterization with MCC, with CC, and without CC/MCC
Open AVR + Open Ablation	216-221	Cardiac Valve and Other Major Cardiothoracic Procedures with or without Cardiac Catheterization with MCC, with CC, and without CC/MCC
Open MVR + Open AVR + Open Ablation	216-221	Cardiac Valve and Other Major Cardiothoracic Procedures with or without Cardiac Catheterization with MCC, with CC, and without CC/MCC

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Since patients can have multiple procedures reported with a principal diagnosis during a particular hospital stay, and a patient can be assigned to only one MS–DRG, the surgical hierarchy GROUPER logic provides a hierarchical order of surgical classes from the most resource-intensive to the least resource-intensive. Patients with multiple procedures are generally assigned to the MS–DRG that correlates to the most resource-intensive surgical class.

As noted in the proposed rule, our clinical advisors reviewed this grouping issue and noted in open concomitant surgical ablation procedures, the CABG, MVR, and/or AVR components of the procedure are more technically complex than the open surgical ablation procedure. We noted that our clinical advisors stated that in open concomitant surgical ablation procedures, the MS–DRG assigned should be based on the most resource-intensive procedure performed. Therefore, we indicated we believed this request would be better addressed by proposing to revise the surgical hierarchy in MDC 05 rather than creating four new MS–DRGs. For FY 2022, we proposed to revise the surgical hierarchy for the MS–DRGs in MDC 05 to sequence MS–DRGs 231–236 (Coronary Bypass) above MS–DRGs 228 and 229 to enable more appropriate MS–DRG assignment for these types of cases. We indicated in the proposed rule, that, under this proposal, if a procedure code describing a CABG and a procedure code describing an open surgical ablation are present, the GROUPER logic would assign the CABG surgical class because a CABG would be sequenced higher in the hierarchy than an open surgical ablation.

Comment: Many commenters agreed with our proposal to revise the surgical hierarchy for the MS–DRGs in MDC 05 to sequence MS–DRGs 231–236 (Coronary Bypass) above MS–DRGs 228 and 229. Some commenters stated the re-sequencing of the CABG MS–DRGs is long overdue. A commenter specifically stated they agreed with CMS' reasoning to revise the surgical hierarchy rather than to create new DRGs and stated from a clinical and payment standpoint, moving CABG MS–DRGs 231–236 above Other Cardiothoracic Procedure MS–DRGs 228–229 aligns the procedures better with their technical complexity and their costs.

Response: We thank the commenters for their support.

Comment: While supporting our proposal, other commenters stated that this proposal does not address the issue of the increased resources required to treat patients with AF that are also a candidate for an open surgical ablation procedure at the same time of their CABG procedure. Some commenters stated that CMS' proposal to revise the surgical hierarchy for CABG procedures does not advance patient access nor allow patients the opportunity to receive these procedures during the

CABG surgical procedure. Another commenter stated that the proposed revision to the surgical hierarchy fails to address the increased costs of cases associated with open concomitant surgical ablation for AF performed during open mitral valve procedures, which are assigned to MS–DRGs 216 through 221. Another commenter stated while they agree that surgical ablation procedures are not as resource intensive as CABG procedures, CMS' proposal does not give consideration to the increased costs the surgical ablation procedure adds to the CABG procedure.

A commenter stated that CMS did not describe its methodology in detail regarding its analysis of the costs associated with performance of open surgical ablation for AF performed concomitantly during open-heart procedures, preventing meaningful public comments. This commenter stated that concomitant surgical ablation does not represent an ''incidental cost'' to a hospital that can be remedied just through changes in the existing surgical hierarchy.

Commenters expressed concern that given the added costs of performing as many as three procedures at the same time, hospitals may more likely schedule the patient for separate procedures even though guidelines of the Society for Thoracic Surgeons and the Heart Rhythm Society recommend performing surgical ablation for AF at the time of open-heart procedures. A commenter stated that facilities receive only one MS–DRG payment when procedures are performed concomitantly and are therefore burdened with absorbing the additional expenses of other services provided, further stating that data have shown that mortality is significantly reduced in the first year following concomitant treatment.

Many commenters urged CMS to either (1) create new MS–DRGs for these open concomitant procedures as originally requested, or (2) assign these procedures to MS–DRGs that consider the added procedure and device costs required. Another commenter requested that CMS create a supplemental payment mechanism that could be modeled based on the respective costs of the individual procedures determined by claims data and then adjusted for efficiencies of a single operative session to facilitate incremental payment when two major procedures are performed during the same hospital admission.

Response: We appreciate the commenters' feedback.

As discussed in section II.D.15. of the preamble of the proposed rule and this final rule, in our proposal to revise the surgical hierarchy for the MS–DRGs in MDC 05, MS–DRGs 216–221 (Cardiac Valve and Other Major Cardiothoracic Procedures) will continue to be sequenced above MS–DRGs 231–236 (Coronary Bypass) and MS–DRGs 228 and 229. Of note, in the absence of other procedure codes on the claim, we agree with the commenter that the only procedure code combination describing open concomitant surgical ablations affected by our proposal to revise the surgical hierarchy for the MS–DRGs in MDC 05 is ''Open CABG + Open Ablation''. Under this proposal, the six other combinations describing open concomitant surgical ablations will continue to be assigned to MS–DRGs 216 through 221.

In response to the comment that CMS did not describe its methodology in detail regarding its analysis of the costs associated with performance of open surgical ablation, as we discussed insection II.D.15. of the preamble of the proposed rule, we reviewed the surgical hierarchy within MDC 05 consistent with our annual process; specifically, we weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class.

With regard to the comments stating that the proposed revision to the surgical hierarchy fails to address the increased costs of cases associated with open concomitant surgical ablation, we examined the data analysis of cases reporting procedure code combinations describing open concomitant surgical ablations in the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting procedure code combinations describing open concomitant surgical ablations. First, we refer the reader to Table 6P.1n associated with this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of ICD–10–PCS procedure codes reflecting mitral valve repair or replacement (MVR), aortic valve repair or replacement (AVR), and coronary artery bypass grafting (CABG) procedures that we examined in our analysis of this issue. We also refer the reader to Table 6P.1o associated with this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for data analysis findings of cases reporting procedure code combinations describing open concomitant surgical ablations currently assigned to MS–DRGs 216, 217, 218, 219, 220 and 221 from the March 2020 update of the FY 2019 MedPAR file and from the September 2020 update of the FY 2020 MedPAR file. We note that if a procedure code combination that is currently assigned to MS–DRGs 216, 217, 218, 219, 220 and 221 is not displayed, it is because there were no cases found reporting that combination in the assigned MS–DRG.

As shown in Table 6P.1o associated with this final rule, in our examination of the claims data from both the March 2020 update of the FY 2019 MedPAR file and September 2020 update of the FY 2020 MedPAR file, while the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all cases in their respective MS–DRG, we found there is variation in the volume, length of stay, and average costs of the cases. In the analysis of claims data from the March 2020 update of the FY 2019 MedPAR file, during our review of MS–DRG 216, we found 1,145 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 17.6 days to 24.3 days and average costs ranging from $77,868 to $125,120 for these cases. For MS–DRG 217, we found 295 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 10 days to 13 days and average costs ranging from $45,526 to $52,859 for these cases. For MS–DRG 218, we found 7 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 7 days to 11 days and average costs ranging from $28,614 to $68,725 for these cases. For MS–DRG 219, we found 2,673 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 11.6 days to 13.3 days and average costs ranging from $65,846 to $83,281 for these cases. For MS–DRG 220, we found 1,890 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 7.3 days to 10.2 days and average costs ranging from $44,568 to $64,726 for these cases. For MS–DRG 221, we found 110 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 5.6 days to 6.8 days and average costs

ranging from $44,826 to $73,629 for these cases.

Our analysis of the claims data from the September 2020 update of the FY 2020 MedPAR file resulted in similar findings to those from the March 2020 update of the FY 2019 MedPAR file; while the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all the cases in their respective MS–DRG, we found there is variation in the volume, length of stay, and average costs of the cases. In the analysis of claims data from the September 2020 update of the FY 2020 MedPAR file, during our review of MS–DRG 216, we found 931 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 16.1 days to 20.5 days and average costs ranging from $79,732 to $108,552 for these cases. For MS–DRG 217, we found 207 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 9.2 days to 12 days and average costs ranging from $46,588 to $70,840 for these cases. For MS–DRG 218, we found 1 case reporting procedure code combinations describing open concomitant surgical ablations with a length of stay of 8 days and costs of $17,611. For MS–DRG 219, we found 1,998 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 11.6 days to 14.6 days and average costs ranging from $68,175 to $104,560 for these cases. For MS–DRG 220, we found 1,318 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 7.5 days to 8.0 days and average costs ranging from $48,200 to $61,444 for these cases. For MS–DRG 221, we found 60 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 5.1 days to 8.6 days and average costs ranging from $49,910 to $65,501 for these cases.

In response to comments that urged CMS to create new MS–DRGs for these open concomitant procedures as originally requested, based on these data, our clinical advisors believe additional time is needed given the complexity of these code combinations and corresponding data before exploring a proposal to create new MS–DRGs for this subset of patients. For example, cases reporting a CABG and a procedure code describing an open surgical ablation without procedure codes describing an AVR or an MVR were found in MS–DRGs 216 through 221 meaning another cardiac valve or other major cardiothoracic procedure was reported, which could be contributing to the increased costs of these cases. Secondly, MS–DRGs 216, 217 and 218 are defined by the performance of cardiac catheterization, meaning a cardiac catherization procedure was reported, which could be also contributing to the increased costs of these cases. Lastly, the cases reporting an open concomitant surgical ablation code combination are predominately found in the higher (CC or MCC) severity level MS–DRGs of their current base MS–DRG assignment. Therefore, our clinical advisors believe that additional time is needed to allow for further analysis of the claims data to determine to what extent the patient's co-morbid conditions are also contributing to higher costs and to identify other contributing factors that might exist with respect to the increased length of stay and costs of these cases in these MS–DRGs. Our clinical advisors also believe that future data findings may demonstrate additional variance in resource utilization for this patient population.

We also note, as discussed in Section D.1.b of the proposed rule and this final rule, using the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, we analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2022. Findings from our analysis indicated that MS–DRGs 216, 217, 218 as well as approximately 31 other MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. We refer the reader to Table 6P.1c associated with the proposed rule and this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of the 96 MS–DRGs that would be subject to deletion and the list of the 58 new MS–DRGs that would have been proposed for creation under this policy if the NonCC subgroup criteria were applied.

As discussed previously, we are finalizing the delay of the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split until FY 2023 or later, and are finalizing our proposal to maintain the current structure of the 32 MS–DRGs that currently have a three-way severity level split (total of 96 MS–DRGs) that would otherwise be subject to these criteria for FY 2022. Noting that currently the total number of cases in MS–DRG 218 is below 500, and that we may consider consolidating these MS–DRGs into two severity levels based on the application of the NonCC subgroup criteria in future rule-making, as well as for the reasons stated previously, we believe additional time is needed to review the clinical nature of cases reporting an open concomitant surgical ablation code combination before creating new MS–DRGs for the subset of cases with procedure codes that describe open concomitant surgical ablation procedures that are currently assigned to MS–DRGs 216 through 221 at this time.

In response to comment that the proposed hierarchy change will not address the increased resources required to treat patients with AF that are a candidate for an open surgical ablation procedure at the same time of their CABG procedure, we analyzed the March 2020 update of the FY 2019 MedPAR file for cases reporting the procedure code combination ''Open CABG + Open Ablation'' of the seven potential procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure, as this is the only concomitant procedure code combination potentially affected by the proposed hierarchy change (in the absence of other procedure codes that could affect MS–DRG assignment on the claim).

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MS-DRGs 228 – 229: Cases Reporting Procedures Describing Open Concomitant Ablation				
MS-DRG		**Number of Cases**	**Average Length of Stay**	**Average Costs**
228	Other Cardiothoracic Procedures with MCC - All Cases	4,436	10.7	$45,772
	Cases with procedure code for CABG and procedure code for open ablation	1,010	12.8	$56,331
229	Other Cardiothoracic Procedures without MCC – All cases	5,250	5.3	$29,454
	Cases with procedure code for CABG and procedure code for open ablation	1,041	8.2	$38,643

As shown in the table, the data analysis performed indicates that the 1,010 cases in MS–DRG 228 reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 228 (12.8 days versus 10.7 days) and higher average costs when compared to all the cases in MS–DRG 228 ($56,331 versus $45,772). The 1,041 cases in MS–DRG 229 reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation also have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 229 (8.2 days versus 5.3 days) and higher average costs when compared to all the cases in MS–DRG 229 ($38,643 versus $29,454). As expected, there were zero cases found with procedure codes describing one of the other six ''open concomitant surgical ablation'' procedure code combinations as described by the requestor since GROUPER logic would assign MS–DRGs 216 through 221 for the other combinations.

We then examined the redistribution of cases that is anticipated to occur as a result of the proposal to move MS–DRGs 231 through 236 (Coronary Bypass) above MS–DRGs 228 and 229 in the surgical hierarchy of MDC 05 for Version 39 of the ICD–10 MS–DRGs, by processing the claims data from the March 2020 update of the FY 2019 MedPAR file through the ICD–10 MS–DRG GROUPER Version 38 and then processing the same claims data through the ICD–10 MS–DRG GROUPER Version 39 for comparison. The number of cases from this comparison that result in different MS–DRG assignments is the number of the cases that are anticipated to potentially shift or be redistributed. Our findings are shown in the following table.

Version 38 MS-DRG	Description	Version 39 MS-DRG	Description	Counts
228	Other Cardiothoracic Procedures with MCC	231	Coronary Bypass with PTCA with MCC	68
		233	Coronary Bypass with Cardiac Catheterization with MCC	740
		235	Coronary Bypass without Cardiac Catheterization with MCC	893
		268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC	9
229	Other Cardiothoracic Procedures without MCC	228	Other cardiothoracic procedures with MCC	21
		232	Coronary Bypass with PTCA without MCC	20
		233	Coronary Bypass with Cardiac Catheterization with MCC	2
		234	Coronary Bypass with Cardiac Catheterization without MCC	556
		236	Coronary Bypass without Cardiac Catheterization without MCC	1,132
		269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC	6

We found a number of cases that are anticipated to potentially shift or be redistributed into MS–DRGs 231 through 236. The largest number of cases moving out of MS–DRG 228 are moving into MS–DRG 235, which means these cases reported a procedure code for CABG and a cardiothoracic procedure, such as a surgical ablation, without procedure codes reporting a PTCA or cardiac catherization. The largest number of cases moving out of MS–DRG 229 are moving into MS–DRG 236, which again means these cases reported a procedure code for CABG and a cardiothoracic procedure, such as a surgical ablation, without procedure codes reporting a PTCA or cardiac catherization.

We then examined the claims data from the March 2020 update of the FY 2019 MedPAR file to identify the average length of stay and average costs for all cases in MS–DRGs 231, 232, 233, 234, 235 and 236. Our findings are shown in the following table.

MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
231	Coronary Bypass with PTCA with MCC	974	12.3	$62,784
232	Coronary Bypass with PTCA without MCC	701	8.5	$43,595
233	Coronary Bypass with Cardiac Catheterization with MCC	12,150	12.7	$54,170
234	Coronary Bypass with Cardiac Catheterization without MCC	13,947	8.7	$38,058
235	Coronary Bypass without Cardiac Catheterization with MCC	11,497	9.8	$42,133
236	Coronary Bypass without Cardiac Catheterization without MCC	19,720	6.4	$29,565

In reviewing the data analysis performed, the 1,010 cases in MS–DRG 228 reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 235 (12.8 days versus 9.8 days) and higher average costs when compared to all the cases in MS–DRG 235 ($56,331 versus $42,133). The 1,041 cases in MS–DRG 229 reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation also have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 236 (8.2 days versus 6.4 days) and higher average costs when compared to all the cases in MS–DRG 236 ($38,643 versus $29,565). The average length of stay and average costs of cases reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation in MS–DRG 228 as well as a secondary diagnosis of MCC are closer aligned to costs of cases in MS–DRGs 233 (Coronary Bypass with Cardiac Catheterization with MCC) (12.8 days versus 12.7 days and $56,331 versus $54,170 respectively). The average length of stay and average costs of cases reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation in MS–DRG 229 without secondary diagnosis of MCC are closer aligned to costs of cases in MS–DRGs

234 (Coronary Bypass with Cardiac Catheterization without MCC) (8.2 days versus 8.7 days and $38,643 versus $38,058 respectively).

Next, we analyzed the September 2020 update of the FY 2020 MedPAR file for cases reporting a procedure code describing a CABG procedure with a procedure code describing an open ablation.

MS-DRGs 228 – 229: Cases Reporting Procedures Describing Open Concomitant Ablation

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
228	Other Cardiothoracic Procedures with MCC - All Cases	4,419	10.2	$46,508
	Cases with procedure code for CABG and procedure code for open ablation	836	12.8	$60,327
229	Other Cardiothoracic Procedures without MCC – All cases	4,732	4.9	$29,885
	Cases with procedure code for CABG and procedure code for open ablation	824	7.9	$39,392

As shown in the table, the data analysis performed indicates that the 836 cases in MS–DRG 228 reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 228 (12.8 days versus 10.2 days) and higher average costs when compared to all the cases in MS–DRG 228 ($60,327 versus $46,508). The 824 cases in MS–DRG 229 reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation also have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 229 (7.9 days versus 4.9 days) and higher average costs when compared to all the cases in MS–DRG 229 ($39,392 versus $29,885). As expected, there were zero cases found with procedure codes describing one of the other six ''open concomitant ablation'' procedure code combinations as described by the requestor since GROUPER logic would assign MS–DRGs 216 through 221 for the other combinations.

As we did with the March 2020 update of the FY 2019 MedPAR file, we then examined the redistribution of cases that is anticipated to occur by processing the claims data, this time from the September 2020 update of the FY 2020 MedPAR file through the ICD–10 MS–DRG GROUPER Version 38 and then processed the same claims data through the ICD–10 MS–DRG GROUPER Version 39 for comparison. Our findings are shown in the table.

Version 38 MS-DRG	Description	Version 39 MS-DRG	Description	Counts
228	Other Cardiothoracic Procedures with MCC	231	Coronary Bypass with PTCA with MCC	86
		233	Coronary Bypass with Cardiac Catheterization with MCC	1,126
		235	Coronary Bypass without Cardiac Catheterization with MCC	1,288
		268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC	21
229	Other Cardiothoracic Procedures without MCC	228	Other Cardiothoracic Procedures with MCC	37
		232	Coronary Bypass with PTCA without MCC	22
		234	Coronary Bypass with Cardiac Catheterization without MCC	769
		235	Coronary Bypass without Cardiac Catheterization with MCC	1
		236	Coronary Bypass without Cardiac Catheterization without MCC	1,420
		269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC	3

Similarly, we found a number of cases that are anticipated to potentially shift or be redistributed into MS–DRGs 231 through 236. The largest number of cases moving out of MS–DRG 228 are moving into MS–DRG 235, which means these cases reported a procedure code for CABG and a cardiothoracic procedure, such as a surgical ablation, without procedure codes reporting a PTCA or cardiac catherization. The largest number of cases moving out of MS–DRG 229 are moving into MS–DRG 236, which again means these cases reported a procedure code for CABG and a cardiothoracic procedure, such as a surgical ablation, without procedure codes reporting a PTCA or cardiac catherization.

We also examined the claims data from the September 2020 update of the FY 2020 MedPAR file to identify the average length of stay and average costs for all cases in MS–DRGs 231, 232, 233, 234, 235 and 236. Our findings are shown in the following table.

MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
231	Coronary Bypass with PTCA with MCC	745	12.4	$65,558
232	Coronary Bypass with PTCA without MCC	569	8.2	$46,079
233	Coronary Bypass with Cardiac Catheterization with MCC	9,572	12.5	$56,388
234	Coronary Bypass with Cardiac Catheterization without MCC	10,324	8.5	$39,406
235	Coronary Bypass without Cardiac Catheterization with MCC	9,371	9.7	$44,106
236	Coronary Bypass without Cardiac Catheterization without MCC	14,534	6.4	$31,170

In reviewing the data analysis performed, the 836 cases in MS–DRG 228 reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 235 (12.8 days versus 9.7 days) and higher average costs when compared to all the cases in MS–DRG 235 ($60,327 versus $44,106). The 824 cases in MS–DRG 229 reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation also have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 236 (7.9 days versus 6.4 days) and higher average costs when compared to all the cases in MS–DRG 236 ($39,392

versus $31,170). The average length of stay and average costs of cases reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation in MS–DRG 228 as well as a secondary diagnosis of MCC are closer aligned to costs of cases in MS–DRGs 233 (Coronary Bypass with Cardiac Catheterization with MCC) (12.8 days versus 12.5 days and $60,327 versus $56,388 respectively). The average length of stay and average costs of cases reporting a procedure code that describes a CABG procedure as well as a procedure code describing an open ablation in MS–DRG 229 without secondary diagnosis of MCC are closer aligned to costs of cases in MS–DRGs 234 (Coronary Bypass with Cardiac Catheterization without MCC) (7.9 days versus 8.5 days and $39,392 versus $39,406 respectively).

In response to comments that urged CMS to assign these procedures to MS–DRGs that consider the added procedure and device costs required, our clinical advisors reviewed these data and continue to state that in open concomitant surgical ablation procedures, the CABG, MVR, and/or AVR components of the procedure are more technically complex than the open surgical ablation procedure. They also state that the proposed revision to the surgical hierarchy leads to a grouping that is more coherent and better accounts for the resources expended to address the more complex procedures from other cases redistributed during the hierarchy change. However, in cases where an open ablation is performed in combination with a coronary bypass procedure but without a PTCA or cardiac catherization procedure also being performed, to better address the concerns expressed in the public comments, our clinical advisors support the assignment of these cases to MS–DRGs 233 and 234 as an enhancement to better reflect the clinical severity and resource use involved in these cases. Our clinical advisors also support changing the titles of MS–DRGs 233 and 234 to ''Coronary Bypass with Cardiac Catheterization or Open Ablation with and without MCC, respectively'' to better reflect the assigned procedures.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to revise the surgical hierarchy for the MS–DRGs in MDC 05 to sequence MS–DRGs 231–236 (Coronary Bypass) above MS–DRGs 228 and 229, effective October 1, 2021. We refer the reader to section II.D.15. of the preamble of this final rule for the discussion of the surgical hierarchy and the complete list of our proposed modifications to the surgical hierarchy in MDC 05 as well as our finalization of that proposal. In addition, after consideration of the public comments we received and for the reasons discussed, we are also finalizing the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS–DRGs 233 and 234 and changing the titles of these MS–DRGs to ''Coronary Bypass with Cardiac Catheterization or Open Ablation with and without MCC, respectively''.

As discussed earlier in the proposed rule and in this section, this request involved two parts. The second part of the request was to reassign cases describing standalone percutaneous endoscopic surgical ablation. According to the requestor, standalone, percutaneous endoscopic surgical ablation is a rapidly growing therapy, indicated for highly symptomatic patients that have already failed medical management and/or percutaneous catheter ablation procedures. The requestor identified nine ICD–10–PCS codes that they stated describe percutaneous endoscopic surgical ablation. These codes and their corresponding MDC and MS–DRG assignments are listed in the following table.

ICD-10-PCS Code	MDC	MS-DRG	Description
02544ZZ	05	228-229	Destruction of coronary vein, percutaneous endoscopic approach
02554ZZ	05	228-229	Destruction of atrial septum, percutaneous endoscopic approach
02564ZZ	05	228-229	Destruction of right atrium, percutaneous endoscopic approach
02574ZK	05	273-274	Destruction of left atrial appendage, percutaneous endoscopic approach
02574ZZ	05	228-229	Destruction of left atrium, percutaneous endoscopic approach
02584ZZ	05	228-229	Destruction of conduction mechanism, percutaneous endoscopic approach
02594ZZ	05	228-229	Destruction of chordae tendineae, percutaneous endoscopic approach
025S4ZZ	04 05	163-165 270-272	Destruction of right pulmonary vein, percutaneous endoscopic approach
025T4ZZ	04 05	163-165 270-272	Destruction of left pulmonary vein, percutaneous endoscopic approach

The requestor performed their own analysis and stated that they found the most common MS–DRG assignment for cases describing standalone percutaneous endoscopic surgical ablation was MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) and that in those MS–DRGs, the standalone surgical ablation procedures cost more than all the procedures in their currently assigned MS–DRGs 228 and

229. Therefore, the requestor recommended CMS reassign these procedures to higher weighted MS–DRGs 219 and 220 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC and with CC, respectively).

In response to this request, we examined claims data from the March 2020 update of the FY 2019 MedPAR file for all cases in MS–DRGs 228 and 229 and compared the results to cases with a procedure code describing a standalone percutaneous endoscopic surgical ablation procedure. Our findings are shown in the following table.

MS-DRGs 228 – 229: Cases Reporting Procedures Describing Percutaneous Endoscopic Surgical Ablation

MS-DRG	ICD-10-PCS codes	Number of Cases	Average Length of Stay	Average Costs
228	All cases	4,436	10.7	$45,772
	Cases with procedure code for percutaneous endoscopic surgical ablation	99	7.1	$48,281
229	All Cases	5,250	5.3	$29,454
	Cases with procedure code for percutaneous endoscopic surgical ablation	497	3.7	$35,516

As shown in the table, the data analysis performed indicates that the 99 cases in MS–DRG 228 reporting a procedure code that describes percutaneous endoscopic surgical ablation have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 228 (7.1 days versus 10.7 days) and higher average costs when compared to all the cases in MS–DRG 228 ($48,281 versus $45,772). The 497 cases in MS–DRG 229 reporting a procedure code that describes percutaneous endoscopic surgical ablation have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 229 (3.7 days versus 5.3 days) and higher average costs when compared to all the cases in MS–DRG 229 ($35,516 versus $29,454).

We then examined the claims data from the March 2020 update of the FY 2019 MedPAR file to identify the average length of stay and average costs for all cases in MS–DRGs 219 and 220. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
219	15,597	10.9	$57,845
220	15,074	6.5	$39,565

As shown in the table, for MS–DRG 219, there were a total of 15,597 cases with an average length of stay of 10.9 days and average costs of $57,845. For MS–DRG 220, there were a total of 15,074 cases with an average length of stay of 6.5 days and average costs of $39,565.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for all cases in MS–DRGs 228 and 229 and compared the results to cases with a procedure code describing a standalone percutaneous endoscopic surgical ablation procedure. Our findings are shown in the following table.

MS-DRGs 228 – 229: Cases Reporting Procedures Describing Percutaneous Endoscopic Surgical Ablation				
MS-DRG	**ICD-10-PCS codes**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
228	All cases	4,419	10.2	$46,508
	Cases with procedure code for percutaneous endoscopic surgical ablation	84	6.9	$44,710
229	All Cases	4,732	4.9	$29,885
	Cases with procedure code for percutaneous endoscopic surgical ablation	393	3.4	$34,237

As shown in the table, the data analysis performed indicates that the 84 cases in MS–DRG 228 reporting a procedure code that describes percutaneous endoscopic surgical ablation have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 228 (6.9 days versus 10.2 days) and lower average costs when compared to all the cases in MS–DRG 228 ($44,710 versus $46,508). The 393 cases in MS–DRG 229 reporting a procedure code that describes percutaneous endoscopic surgical ablation have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 229 (3.4 days versus 4.9 days) and higher average costs when compared to all the cases in MS–DRG 229 ($34,237 versus $29,885).

We then examined the claims data from the September 2020 update of the FY 2020 MedPAR file to identify the average length of stay and average costs for all cases in MS–DRGs 219 and 220. Our findings are shown in the following table.

MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
219	11,863	10.9	$61,934
220	10,072	6.5	$41,800

As shown in the table, for MS–DRG 219, there were a total of 11,863 cases with an average length of stay of 10.9 days and average costs of $61,934. For MS–DRG 220, there were a total of 10,072 cases with an average length of stay of 6.5 days and average costs of $41,800.

As noted in the proposed rule, our analysis indicates that MS–DRGs 219 and 220 generally have much higher average costs and longer average lengths of stay than the cases with a procedure code describing a standalone percutaneous endoscopic surgical ablation procedure currently assigned to MS–DRGs 228 and 229. Instead, the average costs and average length of stay for cases reporting a standalone percutaneous endoscopic surgical ablation appear to be generally more aligned with the average costs and average length of stay for all cases in MS–DRGs 228 and 229, where they are currently assigned. We indicated that our clinical advisors reviewed this issue and did not recommend changing the assignment of procedure codes describing percutaneous endoscopic surgical ablation. Therefore, for the reasons indicated, we proposed to maintain the current structure of MS–DRGs 219 and 220.

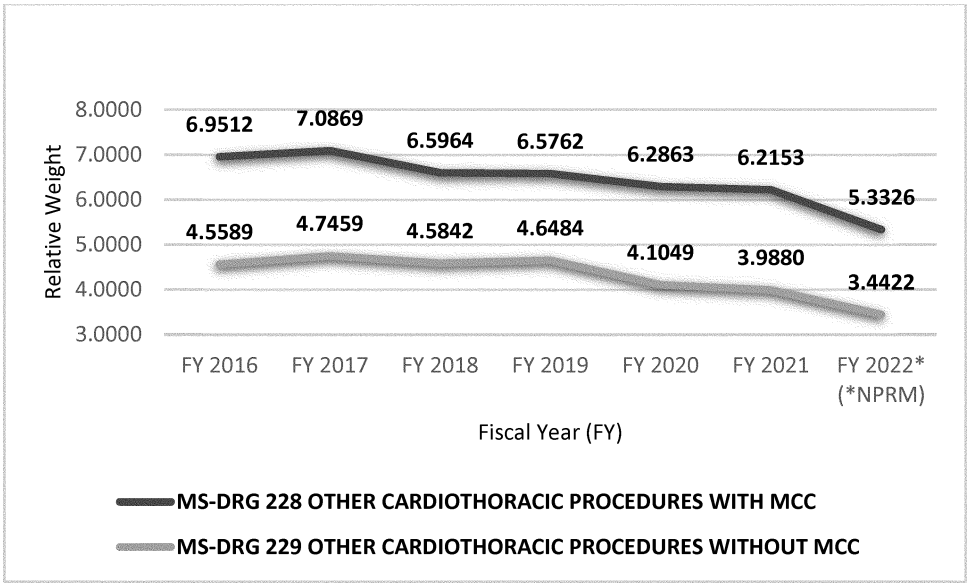
Comment: Commenters disagreed with our proposal to maintain the current structure of MS–DRGs 219 and 220 and noted that payment for MS–DRGs 228 and 229 has been trending downward over the last 5 years. Some commenters stated that CMS did not provide transparency to the details of its analysis to support why standalone hybrid surgical ablation procedures should not be moved from MS–DRGs 228 and 229. Another commenter stated CMS' proposed decline in payment rates makes it impossible for their facility to continue to provide these needed procedures to patients suffering from atrial fibrillation. Another commenter stated the proposed relative weight does not accurately reflect the costs of these device intensive procedures and that there has been no transparency into the cause for these significant declines. Other commenters asserted that hospitals will be forced to postpone or ''trim back'' on providing patients access to more complex, resource intensive procedures such as these, to better align their costs with what they asserted were Medicare's inadequate payment levels. Other commenters requested that CMS use its statutory authority to not reduce the relative weight and payment for MS–DRGs 228 and 229, which contain stand-alone surgical ablation procedures for AF.

Response: We appreciate the commenters' feedback. We note that we did not propose a change to the GROUPER logic of MS–DRGs 228 and 229. Our clinical advisors did not recommend changing the assignment of procedure codes describing percutaneous endoscopic surgical ablation, currently assigned to MS–DRGs 228 and 229, to MS–DRGs 219 and 220. Therefore, we proposed to maintain the current structure of MS–DRGs 219 and 220. This proposal by extension also maintains the current structure of MS–DRGs 228 and 229. With regard to the comments about the implications for payment in MS–DRGs 228 and 229, we note that the goals of assigning or re-assigning procedure codes to MS–DRGs are to better clinically represent the resources involved in caring for these patients and enhance the overall accuracy of the system. In response to the comment that CMS did not provide transparency to

the details of its analysis in the proposed rule, we provided our claims analysis for the cases with a procedure code describing a standalone percutaneous endoscopic surgical ablation procedure as well as a discussion of that analysis and the basis for our proposal. It is unclear from the comments what additional details the commenters are referencing.

In response to the comment that hospitals will be forced to postpone or ''trim back'' on providing patients access to these procedures in order to better align their costs with Medicare payment levels, as we have stated in prior rulemaking, it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that potentially involves increased costs.

As we have indicated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38103), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41273), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42167) and the FY 2021 IPPS/LTCH final rule (85 FR 58598), we do not believe it is normally appropriate to address relative weight fluctuations that appear to be driven by changes in the underlying data even if we have addressed relative weight fluctuations in specific circumstances such as when a relative weight would have declined by more than 20 percent in one year, or in instances where we did not have sufficient MedPAR data to set accurate and stable cost relative weights for low volume MS–DRGs. We do however acknowledge the trending reduction in relative weights for MS–DRGs 228 and 229 in our ratesetting as reflected in the following chart.



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We believe this weight change over time to be appropriately driven by the underlying data in the 5 years since CMS began using the ICD–10 data in calculating the relative weights. We note that there are 809 ICD–10–PCS codes assigned to the GROUPER logic of MS–DRGs 228 and 229 in the ICD–10 MS–DRGs Definitions Manual Version 38.1, of which the procedure codes describing standalone ablation represent a small percentage.

As stated in the ICD–10 MS–DRG Definitions Manual, ''In each MDC there is usually a medical and a surgical class referred to as ''other medical diseases'' and ''other surgical procedures,'' respectively. The ''other'' medical and surgical classes are not as precisely defined from a clinical perspective. The other classes would include diagnoses or procedures which were infrequently encountered or not well defined clinically''. The ICD–10 MS–DRG Definitions Manual also states ''The ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC.'' MS–DRGs 228 and 229 are an example of the surgical MS–DRGs that are found within each MDC that include ''other'' procedures intended to encompass procedures that, while not directly related to the MDC, can and do occur with principal diagnoses in that MDC with sufficient frequency.

As displayed in the proposed rule, when we examined claims data from the March 2020 update of the FY 2019 MedPAR file for all cases in MS–DRGs 228 and 229 and compared the results to cases with a procedure code describing a standalone percutaneous endoscopic surgical ablation procedure, the 99 cases in MS–DRG 228 reporting a procedure code that describes percutaneous endoscopic surgical ablation represent only 2% of the 4,436 total cases in MS–DRG 228. The 497 cases in MS–DRG 229 reporting a procedure code that describes percutaneous endoscopic surgical ablation represent only 9% of the 5,250 total cases in MS–DRG 229.

Similarly, when we examined claims data from the September 2020 update of the FY 2020 MedPAR file for all cases in MS–DRGs 228 and 229 and compared the results to cases with a procedure code describing a standalone percutaneous endoscopic surgical ablation procedure, the 84 cases in MS–DRG 228 reporting a procedure code that describes percutaneous endoscopic surgical ablation represent only 2% of the 4,419 total cases in MS–DRG 228. The 393 cases in MS–DRG 229 reporting a procedure code that describes percutaneous endoscopic surgical ablation represent only 8% of the 4,732 total cases in MS–DRG 229.

We also note that each year, we calculate the relative weights by dividing the average cost for cases within each MS–DRG by the average cost for cases across all MS–DRGs. It is to be expected that when MS–DRGs are restructured, such as when procedure codes are reassigned or the hierarchy within an MDC is revised, resulting in

a different case-mix within the MS–DRGs, the relative weights of the MS–DRGs will change as a result. Over the past five years, there have been changes to the structure of MS–DRGS 228 and 229. Specifically, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56809 through 56813), we finalized our proposal to collapse MS–DRGs 228, 229, and 230 from three severity levels to two severity levels by deleting MS–DRG 230 and revised the structure of MS–DRG 229. We also finalized our proposal to reassign ICD–9–CM procedure code 35.97 and the cases reporting ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) from MS–DRGs 273 and 274 to MS–DRG 228 and revised the titles of MS–DRG 228 and 229. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42080 through 56813) we finalized our proposal to modify the structure of MS–DRGs 266 and 267 by reassigning ICD–10–PCS procedure code 02UG3JZ describing a transcatheter mitral valve repair with implant procedure from MS–DRGs 228 and 229 to MS–DRGs 266 and 267 and revised the titles of MS– DRG 266 and 267. Finally, as discussed in the FY 2022 IPPS/LTCHPPS proposed rule, and earlier in this section, we proposed to revise the surgical hierarchy for the MS–DRGs in MDC 05 to sequence MS–DRGs 231–236 (Coronary Bypass) above MS–DRGs 228 and 229 for FY 2022. Therefore, the data appear to reflect that the difference in the relative weights reflected in Table 5 –List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay associated with final rule for the applicable fiscal year can be attributed to the fact that the finalization of these proposals resulted in a different case-mix within the MS–DRGs which is then being reflected in the relative weights. We refer the reader to section II.E. of the preamble of this FY 2022 IPPS/LTCH PPS final rule for a complete discussion of the relative weight calculations.

Comment: A few commenters noted that hybrid standalone percutaneous endoscopic surgical ablation includes both a minimally invasive surgical ablation performed by a surgeon and catheter ablation performed by an electrophysiologist in the same hospital visit, and stated that the downward payment trend for the MS–DRGs 228 and 229 has resulted in hospitals being undercompensated for the costs of furnishing standalone hybrid percutaneous endoscopic surgical ablation procedures for AF. These commenters proposed two possible remedies to this underpayment, that CMS either (1) maintain the relative weights of MS–DRGs 228 and 229 for a year and then reassess the data, or (2) assign cases reporting procedure codes describing standalone percutaneous endoscopic surgical ablation from MS–DRGs 228 and 229 to the higher (MCC) severity level MS–DRG of its current base MS–DRG assignment, which is MS–DRG 228 (Other Cardiothoracic Procedures with MCC), to prevent underpayment for these procedures.

Response: We appreciate the commenter's suggestions. In response to the request that CMS maintain the relative weights of MS–DRGs 228 and 229 for a year, as stated in response to similar comments expressed by other commenters, we believe the weight change in these MS–DRGs over time to be appropriately driven by the underlying data. In response to the request that CMS assign cases reporting procedure codes describing standalone percutaneous endoscopic surgical ablation from MS–DRGs 228 and 229 to the higher (MCC) severity level MS–DRG of its current base MS–DRG assignment, we examined the claims analysis as presented in the proposed rule and earlier in this section. Using the March 2020 update of the FY 2019 MedPAR file, the 497 cases in MS–DRG 229 reporting a procedure code that describes percutaneous endoscopic surgical ablation without a secondary diagnosis designated as an MCC have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 228 (3.7 days versus 10.7 days) and lower average costs when compared to all the cases in MS–DRG 228 ($35,516 versus $45,772). Similarly, using the September 2020 update of the FY 2020 MedPAR file, the 393 cases in MS–DRG 229 reporting a procedure code that describes percutaneous endoscopic surgical ablation without a secondary diagnosis designated as an MCC have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 228 (3.4 days versus 10.2 days) and lower average costs when compared to all the cases in MS–DRG 228 ($34,237 versus $46,508). Our clinical advisors reviewed this analysis and do not support reassignment of cases reporting a procedure code that describes percutaneous endoscopic surgical ablation without a secondary diagnosis designated as an MCC from MS–DRG 229 to MS–DRG 228 based on this claims data analysis. Our advisors stated it would not be appropriate to reassign these cases into the higher severity level MS–DRG in the absence of an MCC and noted that the cases would not be clinically coherent with regard to resource utilization as reflected in the differences in average costs and average lengths of stay. As additional claims data becomes available, we will continue to analyze the clinical nature of procedure codes that describe percutaneous endoscopic surgical ablation and their MS–DRG assignments to further improve the overall accuracy of the IPPS payments in future rulemaking.

Therefore, after consideration of the public comments we received, and for the reasons stated earlier, we are finalizing our proposal to maintain the current structure of MS–DRGs 219 and 220 for FY 2022.

f. Drug-Eluting Stents

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25121 through 25122), we discussed a request we received to review the MS–DRG assignments of claims involving the insertion of coronary stents in percutaneous coronary interventions. The requestor suggested that CMS eliminate the distinction between drug-eluting and bare-metal coronary stents in the MS–DRG classification. According to the requestor, coated stents have a clinical performance comparable to drug-eluting stents however they are grouped with bare-metal stents because they do not contain a drug. The requestor asserted that this comingling muddies the clinical coherence of the MS–DRG structure, as one cannot infer distinctions in clinical performance or benefits among the groups and potentially creates a barrier (based on hospital decision-making) to patient access to modern coated stents.

The requestor listed the following MS–DRGs in its request.

- MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents);
- MS–DRG 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC);
- MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents); and
- MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC).

According to the requestor, the non-drug-eluting stent MS–DRGs have outlived their usefulness in the stent market. The requestor performed its own analysis of MedPAR data from FY 2015 through FY 2019 and stated that it found the volume of cases describing non-drug-eluting coronary stents has

declined since 2015, culminating in FY 2019, with drug-eluting stents accounting for 96.1% of all stent cases within the Medicare program, while non-drug-eluting stents accounted for only 3.9% that year. The requestor asserted that the assignment of coated stents to the non-drug-eluting stent category creates a market distortion as this newer technology is being comingled with very old technology at a payment disadvantage large enough to influence hospitals' willingness to prescribe, while at the same time acknowledging that the separation in average charges and costs between the non-drug-eluting stent category and the drug-eluting stent category is minimal in their analysis of the claims data.

In the proposed rule, based on a review of the procedure codes that are currently assigned to MS–DRGs 246, 247, 248 and 249, we indicated that our clinical advisors agreed that further refinement of these MS–DRGs may be warranted. However, we noted that in ICD–10–PCS, a stent is considered an intraluminal device. The distinction between drug-eluting and non-drug eluting intraluminal devices is found elsewhere in the ICD–10–PCS procedure code classification and evaluating this request requires a more extensive analysis to assess potential impacts across the MS–DRGs. For these reasons, at this time, we indicated that our clinical advisors recommended that rather than evaluating the procedure codes assigned to MS–DRGs 246, 247, 248 and 249 in isolation, additional analysis should be performed for this subset of procedure codes across the MS–DRGs, as part of the comprehensive procedure code review described in section II.D.11. of the preamble of the proposed rule and this final rule. Therefore, we indicated we believed it would be more appropriate to consider this request further during our comprehensive procedure code review in future rulemaking.

Comment: We received a comment expressing concern that the existence of a payment differential between drug-eluting and bare-metal stents continues to prevent access for patients who are not able to obtain the clinical benefits of modern coated stents due to hospital margin concerns. The commenter stated that multiple clinical studies have consistently proven that the clinical safety and effectiveness of their cardiovascular coated stent is more similar to drug-eluting coronary stents when compared to bare-metal-stents. This commenter urged CMS to take timely action in refining the MS–DRGs to remedy the patient access issue, respectfully requested that CMS complete its analysis in time for the FY 2023 IPPS proposed rule, and also requested that CMS confirm the timing in this FY 2022 IPPS final rule.

Response: We appreciate the commenter's comments. We note that the distinction between drug eluting and non-drug-eluting stents has long existed in the classification. In the FY 2003 IPPS/LTCH PPS final rule (67 FR 50003 through 50005), we created two new temporary CMS DRGs to reflect cases involving the insertion of a drug-eluting coronary artery stent as signified by the presence of code ICD–9–CM procedure code 36.07 (Insertion of drug-eluting coronary artery stent): CMS DRG 526 (Percutaneous Cardiovascular Procedure With Drug- Eluting Stent With AMI); and CMS DRG 527 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent Without AMI) to parallel existing CMS DRGs 516 (Percutaneous Cardiovascular Procedure with Acute Myocardial Infarction (AMI)) and 517(Percutaneous Cardiovascular Procedure with Coronary Artery Stent without AMI). Although the FDA had not yet approved the technology for use, at the time public presentation of the results from clinical trials found virtually no in-stent restenosis in patients treated with the drug-eluting stent. Therefore, we stated temporary CMS DRGs 526 and 527 CMS DRGs were created effective for discharges occurring on or after April 1, 2003 in recognition of the potentially significant impact this technology may conceivably have on the treatment of coronary artery blockages, the predictions of its rapid, widespread use, and that the higher costs of this technology could create undue financial hardships for hospitals due to the high volume of stent cases. The FDA ultimately approved drug-eluting stents for use in April 2003.

In the FY 2006 IPPS/LTCH PPS (70 FR 47292 through 47295), we deleted CMS DRGs 516, 517, 526, and 527 and created four new CMS DRGs in their places. We stated that rather than divide the CMS DRG pairs based on whether the patient had an acute myocardial (AMI), we split each pair of CMS DRGs based on the presence or absence of a major cardiovascular condition to identify subgroups of significantly more severe patients who use greater hospital resources more accurately than was possible under the previous CMS DRGs. The new CMS DRG titles were: CMS DRG 555 (Percutaneous Cardiovascular Procedure with Major Cardiovascular Diagnosis); CMS DRG 556 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without Major Cardiovascular Diagnosis); CMS DRG 557 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with Major Cardiovascular Diagnosis) (formerly CMS DRG 526); and CMS DRG 558 (Percutaneous Cardiovascular Procedure with Drug- Eluting Stent without Major Cardiovascular Diagnosis). In the FY 2008 IPPS/LTCH PPS final rule we adopted the MS–DRGs and in that rule (72 FR 47259 through 47260) we stated we found that PTCAs with four or more vessels or four or more stents were more comparable in average charges to the higher weighted DRG in the group and made changes to the GROUPER logic. Claims containing ICD–9–CM procedure code 00.66 for PTCA, and code 36.07 (Insertion of drug-eluting coronary artery stent(s)), and code 00.43 (Procedure on four or more vessels) or code 00.48 (Insertion of four or more vascular stents) were assigned to MS–DRG 246 (formerly 557). In addition, claims containing ICD–9–CM procedure code 00.66 for PTCA, and code 36.06 (Insertion of non-drug eluting coronary artery stent(s)), and code 00.43 or code 00.48 were assigned to MS–DRG 248 (formerly 555). We also made conforming changes to the MS–DRG titles as follows: MS–DRG 246 was titled ''Percutaneous Cardiovascular Procedures with Drug-Eluting Stent(s) with MCC or 4 or more Vessels/Stents''. MS–DRG 248 was titled ''Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent(s) with MCC or 4 or more Vessels/Stents''. The title for MS–DRGs 247 (formerly 558) and 249 (formerly 556) remained unchanged. In FY 2018 IPPS/LTCH PPS Final rule (82 FR 38024) we finalized our proposal to revise the title of MS– DRG 246 to ''Percutaneous Cardiovascular Procedures with Drug- Eluting Stent with MCC or 4+ Arteries or Stents'' and the title of MS–DRG 248 to ''Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents'' to better reflect the ICD–10–PCS terminology of ''arteries'' versus ''vessels'' as used in the procedure code titles within the classification.

We also again note the distinction between drug-eluting and non-drug eluting intraluminal devices is found elsewhere in the ICD–10–PCS procedure code classification. This distinction is not limited to procedures describing coronary interventions. A more extensive analysis is needed to assess the potential impacts across the MS–DRGs to avoid unintended consequences or missed opportunities in most appropriately capturing the resource utilization and clinical coherence for this subset of procedures.

In response to the commenter's concern that the existence of a payment differential between drug-eluting and bare-metal stents continues to prevent access for patients, as we have stated in prior rulemaking, it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that potentially involves increased costs. In response to the commenter's request that CMS complete its analysis of the classification in time for the FY 2023 IPPS proposed rule, we note that the comprehensive procedure code review will be a multi-year project. As indicated in section II.D.11. of the preamble of the proposed rule and this final rule, we will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

After consideration of the public comments we received, and for the reasons discussed, we are not making changes in this final rule to the MS–DRG assignments of claims involving the insertion of coronary stents in percutaneous coronary interventions, and we will further consider this issue in future rulemaking.

6. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Knee Joint Procedures

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25122), we discussed a request we received to examine the procedure code combinations for procedures describing a right knee joint removal and replacement and procedures describing a left knee joint removal and replacement in MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively). According to the requestor, when using the MS–DRG GROUPER software version 37, the left knee joint procedure combinations group correctly to MS–DRG 468, while the exact same right knee procedure code combinations group incorrectly to MS–DRG 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders without CC/MCC).

The requestor provided the following procedure codes that describe the procedure code combinations for the left knee joint removal and replacement procedures currently assigned to MS–DRGs 466, 467, and 468.

BILLING CODE 4120–01–P

ICD-10-PCS Code	Description	*with*	ICD-10-PCS Code	Description
0SPD4JC	Removal of synthetic substitute from left knee joint, patellar surface, percutaneous endoscopic approach	*with*	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach
0SPU4JZ	Removal of synthetic substitute from left knee joint, femoral surface, percutaneous endoscopic approach	*with*	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach
0SPW4JZ	Removal of synthetic substitute from left knee joint, tibial surface, percutaneous endoscopic approach	*with*	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach

BILLING CODE 4120–01–C

The requestor also provided the following procedure codes that describe the procedure code combinations for right knee joint removal and replacement procedures for CMS' review and consideration.

BILLING CODE 4120–01–P

ICD-10-PCS Code	Description	*with*	ICD-10-PCS Code	Description
0SPC4JC	Removal of synthetic substitute from right knee joint, patellar surface, percutaneous endoscopic approach	*with*	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPT4JZ	Removal of synthetic substitute from right knee joint, femoral surface, percutaneous endoscopic approach	*with*	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPV4JZ	Removal of synthetic substitute from right knee joint, tibial surface, percutaneous endoscopic approach	*with*	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach

BILLING CODE 4120–01–C

In the proposed rule, we noted that we reviewed the procedure code combinations listed and agree with the requestor that the procedure codes that describe the procedure code combinations for right knee joint removal and replacement procedures were inadvertently excluded from the logic for MS–DRGs 466, 467, and 468.

We also noted that during our review of the previously listed procedure code combinations describing removal and replacement of the right and left knee joints, we identified additional MS–DRGs in which the listed procedure code combinations for the left knee joint are in the logic, however, the listed procedure code combinations for the right knee joint were inadvertently excluded from the logic. Specifically, the listed procedure code combinations describing removal and replacement of the left knee joint are also included in the logic for case assignment to MS–DRGs 461 and 462 (Bilateral or Multiple Major Joint Procedures of Lower Extremity with and without MCC, respectively) in MDC 08 and in the logic for case assignment to MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders). Our clinical advisors stated that the procedure code combinations describing removal and replacement of the right knee joint should be added to MS–DRGs 461, 462, 466, 467, and 468 in MDC 08 and MS–DRGs 628, 629, and 630 in MDC 10 for consistency with the procedure code combinations describing removal and replacement of the left knee joint that are currently assigned to those MS–DRGs. We stated that adding these procedure codes will improve clinical coherence and ensure more appropriate MS–DRG assignment for these cases.

Therefore, for FY 2022, we proposed to add the three procedure code combinations listed previously describing removal and replacement of the right knee joint that were inadvertently omitted from the logic to MS–DRGs 461, 462, 466, 467, and 468 in MDC 08 and MS–DRGs 628, 629, and 630 in MDC 10.

Comment: Several commenters supported the proposal to add the three procedure code combinations listed previously describing removal and replacement of the right knee joint that were inadvertently omitted from the logic to MS–DRGs 461, 462, 466, 467, and 468 in MDC 08 and to MS–DRGs 628, 629, and 630 in MDC 10. A few commenters also recommended that CMS conduct further review to determine whether additional combinations may be currently excluded from the logic for these MS–DRGs.

Another commenter who supported our proposal stated they found the following 11 additional combinations that appeared to be missing from the logic for MS–DRGs 628, 629, and 630 in MDC 10.

BILLING CODE 4120–01–P

ICD-10-PCS Code	Description	*with*	ICD-10-PCS Code	Description
0SPC0JC	Removal of synthetic substitute from right knee joint, patellar surface, open approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPC0JZ	Removal of synthetic substitute from right knee joint, open approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPC0LZ	Removal of medial unicondylar synthetic substitute from right knee joint, open approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPC0MZ	Removal of lateral unicondylar synthetic substitute from right knee joint, open approach	with	0SRV0JZ	replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPC0NZ	Removal of patellofemoral synthetic substitute from right knee joint, open approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPC4JZ	Removal of synthetic substitute from right knee joint, percutaneous endoscopic approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPC4LZ	Removal of medial unicondylar synthetic substitute from right knee joint, percutaneous endoscopic approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPC4MZ	Removal of lateral unicondylar synthetic substitute from right knee joint, percutaneous endoscopic approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPC4NZ	Removal of patellofemoral synthetic substitute from right knee joint, percutaneous endoscopic approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPT0JZ	Removal of synthetic substitute from right knee joint, femoral surface, open approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPV0JZ	Removal of synthetic substitute from right knee joint, tibial surface, open approach	with	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach

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This commenter also noted the difficulty in analyzing the logic list as some code combinations display the Removal code first and other

combinations display the Replacement code first.

Response: We appreciate the commenters' support. We thank the commenters for their feedback and agree with the commenter's findings of the 11 additional code combinations inadvertently missing from the logic for MS–DRGs 628, 629, and 630 in MDC 10. We performed further analysis to determine if other combinations may be inadvertently missing and did not find any.

In response to the commenter's feedback regarding the format in which the Removal and Replacement codes are displayed in the logic, we note that we are working with our contractor, 3M HIS, to evaluate modifications to the logic list in these MS–DRGs that are defined by such combinations and reflected in the ICD–10 MS–DRG Definitions Manual to refine how the logic list may be better displayed.

After consideration of the public comments received, we are finalizing our proposal to add the three procedure code combinations listed previously describing removal and replacement of the right knee joint that were inadvertently omitted from the logic to MS–DRGs 461, 462, 466, 467, and 468 in MDC 08 and MS–DRGs 628, 629, and 630 in MDC 10 and are adding the 11 additional code combinations listed that were provided by the commenter to the logic for MS–DRGs 628, 629, and 630 in MDC 10 for FY 2022.

b. Pelvic Trauma With Internal Fixation

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25123), we discussed a request we received to reassign cases reporting a diagnosis code describing a pelvic fracture in combination with a procedure code describing repair of a pelvic fracture with internal fixation, from the lower (NonCC) severity level MS–DRG of its current base MS–DRG assignment to the higher (MCC) severity level MS–DRG of its current base MS–DRG assignment. According to the requestor, there has been steady growth in the volume of internal fixation procedures performed for pelvic fractures since 2008. The requestor stated that due to this growth rate and the anticipated increase in utilization of these internal fixation devices in these procedures in the future that CMS should reconsider the payment structure for these cases it referred to as ''internal fixation for pelvic trauma''.

The requestor provided data for the Healthcare Common Procedural Coding System (HCPCS) code G0413 (Percutaneous skeletal fixation of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, (includes ileum, sacroiliac joint and/or sacrum) and Current Procedural Terminology (CPT) code 22848 (Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum) from 2008 through 2018 that it cross walked to ICD–10–PCS procedure codes. The requestor stated that this CPT coded data indicated that physicians have used pelvic fracture fixation, and pelvic instrumentation, for an increasing number of trauma/fracture repair cases, demonstrating expanded use of these devices in the pelvic area overall.

The requestor reported that sacral fractures are often underdiagnosed and once the diagnosis is made, bedrest is common, although prolonged bedrest is not recommended for the elderly. In addition, the requestor stated that pelvic fractures may be isolated or they may be associated with surrounding structures. For example, the requester reported that the sacroiliac joint is involved in approximately 30 to 35% of pelvic fracture cases. According to the requestor, the standard of care has also transitioned, from bedrest-only to surgery, and current medical practice has evolved to lower the threshold for fracture repair surgery. For instance, the requestor stated that smaller 5mm fractures that were once left untreated now have standard treatment protocols involving the use of pelvic instrumentation. As a result, the requestor asserted that there will be greater utilization of internal fixation devices to treat these smaller pelvic fractures.

The requestor provided the following procedure codes that it stated describe procedures involving the use of internal fixation devices for pelvic fracture repair.

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ICD-10-PCS Code	Description
0QS204Z	Reposition right pelvic bone with internal fixation device, open approach
0QS234Z	Reposition right pelvic bone with internal fixation device, percutaneous approach
0QS304Z	Reposition left pelvic bone with internal fixation device, open approach
0QS334Z	Reposition left pelvic bone with internal fixation device, percutaneous approach
0SG704Z	Fusion of right sacroiliac joint with internal fixation device, open approach
0SG734Z	Fusion of right sacroiliac joint with internal fixation device, percutaneous approach
0SG804Z	Fusion of left sacroiliac joint with internal fixation device, open approach
0SG834Z	Fusion of left sacroiliac joint with internal fixation device, percutaneous approach

BILLING CODE 4120–01–C

The requestor also provided the following diagnosis code subcategories that it stated identify diagnoses describing pelvic fracture.

BILLING CODE 4120–01–P

ICD-10-CM Subcategory	Description
S32.1 -	Fracture of sacrum
S32.2 -	Fracture of coccyx
S32.3 -	Fracture of ilium

BILLING CODE 4120–01–C

The requestor performed its own analysis of claims data and reported findings for cases reporting a combination of the diagnosis codes found in the listed diagnosis code subcategories and the listed procedure codes (internal fixation for pelvic trauma) for MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively). According to the requestor, its findings support reassignment of these internal fixation for pelvic trauma cases from the lower severity level MS–DRG 517 to the higher severity level MS–DRG 515, from the lower severity level MS–DRG 909 to the higher severity level 907, and from the lower severity level MS–DRG 959 to the higher severity level 957. The requestor suggested that approximately 2,000 cases would be impacted by its recommendation to reassign internal fixation for pelvic trauma cases. The requestor also stated that these internal fixation for pelvic trauma cases currently result in a high rate of CMS outlier payments to institutions that perform a high volume of these procedures. Finally, the requestor stated that there is precedent for reassignment of cases from the lower severity level MS–DRGs to the higher severity level MS–DRG for cases involving the use of a device in orthopedic surgery. The requestor provided the examples of total ankle replacement procedures, spinal disc replacement procedures and neurostimulator implantation procedures to demonstrate how CMS has previously reassigned cases from the lower severity level MS–DRG to the higher severity level MS–DRG.

We noted in the proposed rule that we first examined the claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for all cases in MS–DRGs 515, 516, and 517; MS–DRGs 907, 908, and 909; and MS–DRGs 957, 958, and 959. Our findings are shown in the following tables.

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March 2020 Update of the FY 2019 MedPAR File			
MS-DRG	Number of cases	Average Length of Stay	Average Costs
515 – All cases	4,831	8.2	$22,403
516 – All cases	14,089	4.6	$14,310
517 – All cases	12,675	2.6	$10,316
907 – All cases	10,342	9.6	$28,037
908 – All cases	9,129	5.2	$14,681
909 – All cases	2,994	2.9	$10,078
957 – All cases	2,325	13.1	$54,500
958 – All cases	1,845	8.2	$30,973
959 – All cases	130	5.1	$20,204

September 2020 Update of the FY 2020 MedPAR File			
MS-DRG	**Number of cases**	**Average Length of Stay**	**Average Costs**
515 – All cases	3,691	8.0	$23,094
516 – All cases	10,582	4.6	$15,308
517 – All cases	8,203	2.6	$11,301
907 – All cases	8,706	9.2	$28,127
908 – All cases	7,434	5.1	$15,222
909 – All cases	2,080	2.8	$10,650
957 – All cases	2,028	12.9	$56,366
958 – All cases	1,500	7.9	$32,638
959 – All cases	126	4.7	$18,423

BILLING CODE 4120–01–C

We then examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting any combination of the diagnosis and procedure codes that the requestor provided to identify internal fixation for pelvic trauma cases in MS–DRGs 515, 516, and 517; MS–DRGs 907, 908, and 909; and MS–DRGs 957, 958, and 959.

We noted in the proposed rule that our analysis identified two types of cases in which the combination of a diagnosis code and a procedure code (that the requestor provided to identify internal fixation for pelvic trauma cases) was reported. The first type of case consisted of a diagnosis code describing a pelvic fracture reported in combination with a single procedure code describing repair of a pelvic fracture with internal fixation on a claim, and the second type of case consisted of a diagnosis code describing a pelvic fracture reported in combination with two procedure codes describing repair of a pelvic fracture with internal fixation (for example, one for the right side and one for the left side) on a claim. These cases are described as single and bilateral internal fixation procedures for pelvic trauma, respectively. We refer the reader to Tables 6P.1h and 6P.1i associated with the proposed rule and this final rule (which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of diagnosis and procedure code combinations reflecting single internal fixation for pelvic trauma procedures reported by case ID in each MS–DRG, by fiscal year, along with the detailed claims analysis. We refer the reader to Tables 6P.1j and 6P.1k associated with the proposed rule and this final rule (which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of diagnosis and procedure code combinations reflecting bilateral internal fixation for pelvic trauma procedures reported by case ID in each MS–DRG, by fiscal year, along with the detailed claims analysis. For example, Table 6P.1h shows the claims data analysis findings from the March 2020 update of the FY 2019 MedPAR file. Line 2 identifies the section for single cases reported in MS–DRG 515, line 13 identifies the section for single cases reported in MS–DRG 516, and line 42 identifies the single cases reported in MS–DRG 517. The following table summarizes the information found in each column of the tables.

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Column	Description
A	Case ID (identification) assigned
B	MS-DRG
C	ICD-10-CM code reported as the principal diagnosis
D	Description of the ICD-10-CM diagnosis code
E	ICD-10-PCS code reported for procedure
F	Description of the ICD-10-PCS procedure code
G	Case count
H	Average length of stay for case in days
I	Average costs for case
J	Frequency of procedure reported for case
K	Length of stay for case in days
L	Cost of case

BILLING CODE 4120–01–C

As shown in Table 6P.1h, line 4, column A, displays the Case ID ''Single-A'' for the first case; column B displays MS–DRG 515; column C displays the diagnosis code S32.111A; column D displays the description of the diagnosis code (Minimally displaced Zone 1 fracture of sacrum, initial encounter for closed fracture); column E displays the procedure code 0QS234Z; column F displays the description of the procedure code (Reposition right pelvic bone with internal fixation device, percutaneous approach); column G displays the case count 1; column H displays an average length of stay of 3.0 days ; column I displays average costs of $8,433 for the case; column J displays the frequency of the procedure reported was one (1) occurrence; column K displays a 3.0 day length of stay for the case; and column L displays $8,433 for the cost of the case.

We also noted that in our analysis of the claims data from the March 2020 update of the FY 2019 MedPAR file, we found that there were no cases reporting any combination of the diagnosis codes and procedure codes previously listed in MS–DRGs 907, 908, and 909 or MS–DRGs 957, 958, and 959. Our findings are shown in the following table for any cases found to report a diagnosis code describing a pelvic trauma in combination with a procedure code describing single internal fixation in MS–DRGs 515, 516, and 517.

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March 2020 Update of the FY 2019 MedPAR File			
MS-DRG	**Number of cases**	**Average Length of Stay**	**Average Costs**
515 – All cases	4,831	8.2	$22,403
515 – Cases with single internal fixation for pelvic trauma	6	5.67	$28,368
516 – All cases	14,089	4.6	$14,310
516 – Cases with single internal fixation for pelvic trauma	20	5.8	$12,879
517 – All cases	12,675	2.6	$10,316
517 – Cases with single internal fixation for pelvic trauma	3	5.33	$12,147

BILLING CODE 4120–01–C

As shown in the table, there were only three cases found in MS–DRG 517 reporting single internal fixation for pelvic trauma procedures, with an average length of stay of 5.33 days and average costs of $12,147. The average length of stay is longer and the average costs of these three cases higher compared to the average length of stay and the average costs for all cases in MS–DRG 517 (5.33 days versus 2.6 days and $12,147 versus $10,316, respectively); however, overall, we believe the data findings are comparable. We stated that our clinical advisors did not support reassignment of the three cases from MS–DRG 517 to MS–DRG 515 based on the claims data analysis and also stated it would not be appropriate to reassign these cases into the higher severity level MS–DRG in the absence of a MCC and noted that the cases would not be clinically coherent with regard to resource utilization.

In the proposed rule we noted that in our analysis of the claims data from the March 2020 update of the FY 2019 MedPAR file for cases in which a bilateral internal fixation for pelvic trauma procedure was performed, we identified one case in MS–DRG 517. As shown in Table 6P.1j, the average length of stay for this case was 4.0 days and the average costs were $24,258, which is longer than the average length of stay and greater than the average costs for all cases in MS–DRG 517 (2.6 days and $10,316, respectively). We also identified cases reporting various code combinations for MS–DRGs 515 and 516, and provide the details in Table 6P.1j associated with the proposed rule and this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*).

We also noted that in our analysis of the claims data from the September 2020 update of the FY 2020 MedPAR file we found that there were no cases reporting any combination of the diagnosis codes and procedure codes previously listed in MS–DRG 909 or in MS–DRGs 957, 958, and 959. Our findings are shown in the following table for any cases found to report a diagnosis code describing a pelvic trauma in combination with a procedure code describing single internal fixation in MS–DRGs 515, 516, 517, 907, and 908.

BILLING CODE 4120–01–P

September 2020 Update of the FY 2020 MedPAR File			
MS-DRG	**Number of cases**	**Average Length of Stay**	**Average Costs**
515 - All cases	3,691	8.0	$23,094
515 - Cases with single internal fixation for pelvic trauma	6	8.3	$17,356
516 - All cases	10,582	4.6	$15,308
516 - Cases with single internal fixation for pelvic trauma	20	4.35	$14,163
517- All cases	8,203	2.6	$11,301
517 - Cases with single internal fixation for pelvic trauma	4	2.5	$10,136
907 - All cases	8,706	9.2	$28,127
907 - Cases with single internal fixation for pelvic trauma	1	25.0	$97,152
908 - All cases	7,434	5.1	$15,222
908 - Cases with single internal fixation for pelvic trauma	1	6.0	$19,741

BILLING CODE 4120–01–C

As shown in the table, there were only four cases found in MS–DRG 517 reporting single internal fixation for pelvic trauma procedures, with an average length of stay of 2.5 days and average costs of $10,136. For the same reasons described previously based on the FY 2019 analysis, our clinical advisors did not support reassignment of the cases in the lower severity level MS–DRG 517 to the higher severity level MS–DRG 515. In addition, the average length of stay and average costs for these four cases reporting single internal fixation for pelvic trauma procedures are less than the average length of stay and average costs for all the cases in MS–DRG 517 (2.5 days versus 2.6 days and $10,136 versus $11,301, respectively); however, overall, we believe the data findings are comparable.

As indicated in the proposed rule, in our analysis of the claims data from the September 2020 update of the FY 2020 MedPAR file for cases in which a bilateral internal fixation for pelvic trauma procedure was performed, we identified one case in MS–DRG 517. As shown in Table 6P.1k, the average length of stay for this case was 2.0 days and the average costs were $10,103, which is shorter than the average length of stay and less than the average costs for all cases in MS–DRG 517 (2.6 days and $11,301, respectively). We also identified cases reporting various combinations for MS–DRGs 515, 516 and MS–DRG 907, and provide the details in Table 6P.1k associated with the proposed rule and this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*).

We stated we believe further analyses of these internal fixation for pelvic trauma cases in the claims data is warranted. We noted that our analysis for both the single and bilateral cases was centered on the reporting of a principal diagnosis code describing a pelvic trauma (fracture) in combination with a procedure code describing internal fixation based on the codes provided by the requestor. However, we also identified cases in the claims data in which a pelvic trauma diagnosis code was reported as a secondary diagnosis code in combination with a procedure code describing internal fixation and believe these cases require further evaluation. In addition, during our review of the diagnosis and procedure codes that the requestor provided, we identified diagnosis codes that we believe do not warrant consideration for purposes of this request and additional procedure codes that describe internal fixation for pelvic trauma procedures, which we believe do warrant further analysis. For example, as previously noted, the requestor provided the subcategories for the diagnosis codes that it requested we consider for analysis. We do not agree that diagnosis codes describing a pelvic fracture that include the term ''sequela'' should be considered in the analysis to examine this request because, in the ICD–10–CM classification, the term sequela is defined as the residual effect (condition produced) after the acute phase of an illness or injury has terminated.

As noted in the proposed rule, we referred the reader to Table 6P.1g for the list of diagnosis codes that are included in the diagnosis subcategories provided by the requestor and the list of procedure codes provided by the requestor, which also contains the procedure codes we identified. We stated that additional time is needed for data analysis given the volume of these code combinations and corresponding data. We also stated we believe that additional time is needed to allow for further analysis of the claims data to determine the causes of the fractures and other possible contributing factors with respect to the length of stay and costs of these cases, as well as the rate of outlier payments as identified by the requestor. We noted that our clinical advisors also believe that future data findings may demonstrate additional variance in resource utilization for this patient population. We further noted that, as discussed in the FY 2021 IPPS/LTCH PPS final rule, we finalized the addition of 161 procedure codes to MS–DRGs 957, 958, and 959 in MDC 24 (Multiple Significant Trauma) that include the insertion of internal fixation devices. We stated we believe it would be beneficial to examine future claims data to determine if there is a change in the volume of cases in those specific MS–DRGs as a result of that update. For these reasons, we proposed to maintain the structure of MS–DRGs 515, 516, and 517; MS–DRGs 907, 908, and 909; and MS–DRGs 957, 958, and 959 for FY 2022.

Comment: Some commenters agreed with CMS that additional analysis would be beneficial for the reasons discussed in the proposed rule. A commenter also suggested that as part of the additional analysis, CMS should also analyze cases involving trauma activations. According to the commenter, the most common reason for treatment of Medicare patients by a trauma center is falls with a high rate of associated fractures, especially hip fractures. This commenter stated that in

addition to trauma programs' readiness, activation and coordinated care, designated and verified programs are required to engage in injury prevention. The commenter further stated their belief that since falls are the single largest traumatic event for Medicare beneficiaries and trauma centers, CMS should engage in policies designed to prevent falls and mitigate the incidence of hip and extremity fractures which are a major source of disability for seniors. The commenter provided examples such as making beneficiary data available on ED visits and hospital admissions for falls sorted by geographic location and the treating hospital and including the source of admission for these beneficiaries. The commenter stated that with appropriate incentives, hospitals could direct injury prevention efforts in collaboration with community organizations, nursing facilities and senior centers to assist with proven fall prevention interventions such as installing safety equipment (for example, grab bars and railings), introducing exercise programs and promoting safe routines for activities of daily living. The commenter also stated that other approaches could involve providing payment for prevention activities targeted at patients who present with a first or recurrent fall in an attempt to avoid a future, more severe injury that could result in a debilitating hip and/or extremity fracture. This commenter expressed interest in collaborating further with CMS and other stakeholders on these initiatives.

Response: We appreciate the commenters' support. We also thank the commenter for their recommendation to examine trauma activation in connection with the additional analysis planned for pelvic fracture repair cases and for the various options presented for injury prevention strategies. We look forward to further engagement with stakeholders on this topic.

Comment: Other commenters suggested that CMS reconsider the request to reassign cases reporting a diagnosis code describing a pelvic fracture in combination with a procedure code describing repair of a pelvic fracture with internal fixation, from the lower (NonCC) severity level MS–DRG of its current base MS–DRG assignment to the higher (MCC) severity level MS–DRG for FY 2022. According to a commenter, as new technologies are made available intended to surgically treat many pelvic fracture patients who previously may have been treated medically in the inpatient setting, hospitals may bear a disproportionate share of these costs until the MS–DRGs are calibrated. This commenter stated that providing a reassignment now would help mitigate the financial strain for hospitals supporting these procedure types, and would benefit the Medicare program in its potential to reduce outlier payments. The commenter maintained that CMS could initially limit the reassignment to specific DRGs, or to specific combinations of procedure and diagnosis codes at this time, and review the data in a future rulemaking period.

Another commenter conducted its own analysis and indicated its findings support reassignment for FY 2022. Alternatively, this commenter also stated they looked forward to updating CMS with additional data to support future reassignment options.

Response: We appreciate the commenters' feedback and the additional analysis conducted. It is not clear from the commenter's analysis which specific code combinations generated the results provided. As we noted in the proposed rule, among other factors, there are specific codes and code combinations requiring further review as we identified additional codes that the requestor did not include in their initial submission. We will continue to work with stakeholders as we evaluate the data for these cases and consider future modifications to the structure of the MS–DRGs.

After consideration of the public comments received, we are finalizing our proposal to maintain the structure of MS–DRGs 515, 516, and 517; MS–DRGs 907, 908, and 909; and MS–DRGs 957, 958, and 959 for FY 2022.

7. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Chronic Renal Replacement Therapy (CRRT)

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25128 through 25138), we discussed a request we received to create new MS–DRGs for cases where the patient receives continuous renal replacement therapy (CRRT) during the inpatient stay. According to the requestor, hospitals incur higher costs related to CRRT and current MS–DRG definitions do not adequately account for the clinical and resource requirements of CRRT. The requestor stated Medicare payment is insufficient to cover the costs of administering CRRT, creating a disincentive in offering this dialysis modality and is a barrier to further adoption of CRRT. The requestor suggested that the following two new MS–DRGs be created:

- Suggested New MS–DRG XXX—Continuous Renal Replacement Therapy with CC/MCC; and
- Suggested New MS–DRG XXX—Continuous Renal Replacement Therapy without CC/MCC.

Renal replacement therapy (RRT) replaces kidney function by exchanging solute and removing fluid from the blood as a means to prevent or treat renal failure in patients with acute kidney injury (AKI). Modalities of renal support include CRRT, conventional intermittent hemodialysis (IHD), and prolonged intermittent renal replacement therapies (PIRRTs), which are a hybrid of CRRT and IHD. IHD provides solute clearance and filtration during relatively brief treatment sessions, generally lasting from three to five hours. CRRT provides gradual fluid removal and solute clearance over prolonged treatment times, typically over a 24-hour period, mimicking the natural function of the kidney to allow for the continuous removal or replacement of fluid. The most common CRRT modalities are continuous venovenous hemofiltration, continuous venovenous hemodialysis, and continuous venovenous hemodiafiltration.

According to the requestor, CRRT is used primarily to treat critically ill, hospitalized patients who experience AKI requiring more intensive and continuous treatment than other dialysis modalities. The requestor stated that CRRT offers fluid balance and convective clearance that may be precisely adjusted for each patient, and has been associated with a higher likelihood of kidney recovery as compared to other modalities of RRT. The requestor asserted that IHD may worsen the neurological status of patients with acute brain injury or other causes of increased intracranial pressure by compromising their cerebral perfusion by raising intracranial pressure. The ongoing modulation of fluid balance and targeted fluid management capabilities of CRRT enables its use in situations other than renal failure. According to the requestor, CRRT, a slow continuous therapy, is preferred for patients who are hemodynamically unstable because it helps prevent the hemodynamic fluctuations common with the more rapid IHD. In light of the COVID–19 pandemic, the requestor noted the National Institutes of Health's Coronavirus Disease 2019 (COVID–19) Treatment Guidelines and The American Society of Nephrology recommend CRRT as the preferred renal replacement therapy for critically ill, COVID–19 patients experiencing AKI, who develop indications for renal replacement therapy, due to the

hemodynamic instability often experienced in this condition.

The requestor acknowledged that under the current MS–DRG definitions, Medicare cases with beneficiaries receiving CRRT are assigned to more than 300 MS–DRGs. Although these beneficiaries are clinically similar in that they are critically ill patients who experience AKI requiring more intensive and continuous treatment than other dialysis modalities, the principal diagnoses for their inpatient stays vary. The requestor stated their analysis of the variability in principal diagnosis of the cases examined with beneficiaries receiving CRRT indicated that, in general, IHD tends to be used more for patients with chronic illnesses, and CRRT tends to be used for more acute injuries and end of life scenarios. Therefore, the requestor suggested that CMS create new MS–DRGs specific to CRRT, without regard to principal diagnosis, in order to group the resource intensive, clinically coherent, CRRT cases together in contrast to the existing GROUPER definitions.

According to the requestor, continuing to assign CRRT to existing MS–DRGs would be clinically inappropriate and remain financially devastating to providers even when treating the most routine, uncomplicated CRRT patients. The requestor performed its own data analysis and stated hospitals lose over $22,000 per CRRT case on average, even when outliers are considered, which they state is a shortfall of more than 30 percent. The requestor asserted these losses create a disincentive for providers to offer CRRT despite its clinical benefits. The requestor also asserted the magnitude of financial losses associated with the provision of CRRT at the current level of MS–DRG payment could force many hospitals to examine the capacity and scope of their CRRT programs if facilities continue to determine that the financial burden of treating Medicare beneficiaries with CRRT is more than the facility can sustain. As COVID–19 continues to strain hospital resources, the requestor asserts the availability of CRRT should not be impeded by inadequate MS–DRG payments related to CRRT.

In the proposed rule, we noted that the following ICD–10–PCS procedure code identifies the performance of CRRT.

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ICD-10-PCS Code	Code Description
5A1D90Z	Performance of urinary filtration, continuous, greater than 18 hours per day

BILLING CODE 4120–01–C

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure code 5A1D90Z is currently recognized as a non-O.R. procedure that affects the MS–DRG to which it is assigned. We indicated that our clinical advisors agreed that the principal diagnosis assigned for inpatient admissions where continuous renal replacement of therapy is utilized can vary. To examine the impact of the use of CRRT in response to this request, we examined claims data from the March 2020 update of the FY 2019 MedPAR file for the top ten MS–DRGs reporting the use of CRRT. Our findings are reflected in the following table:

BILLING CODE 4120–01–P

Top 10 MS-DRGs Reporting Continuous Renal Replacement Therapy					
MS-DRG	**Description**		**Number of Cases**	**Average Length of Stay**	**Average Costs**
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC	All cases	609,320	6.2	$13,338
		Cases with CRRT	2,912	7.9	$27,681
870	Septicemia Or Severe Sepsis with MV >96 Hours	All cases	32,497	14.5	$44,878
		Cases with CRRT	1,731	15.9	$60,478
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC	All cases	85,196	12.5	$34,178
		Cases with CRRT	1,470	17.4	$69,966
003	ECMO or Tracheostomy with MV >96 hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures	All cases	14,532	30.2	$128,196
		Cases with CRRT	1,459	33.4	$174,085
291	Heart Failure and Shock with MCC	All cases	394,415	5.1	$9,668
		Cases with CRRT	660	11.9	$34,628
004	Tracheostomy with MV >96 hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures	All cases	12,702	24.5	$77,393
		Cases with CRRT	463	35.5	$138,940
207	Respiratory System Diagnosis with Ventilator Support >96 Hours	All cases	18,412	14	$39,929
		Cases with CRRT	458	16.8	$61,632
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	All cases	15,597	10.9	$57,845
		Cases with CRRT	442	17.1	$98,802
270	Other Major Cardiovascular Procedures with MCC	All cases	18,959	9.5	$37,249
		Cases with CRRT	430	14.8	$70,030
682	Renal Failure with MCC	All cases	103,511	5.7	$10,486
		Cases with CRRT	401	9.8	$29,089

BILLING CODE 4120–01–C

As shown in this table, our data findings demonstrate the average lengths of stay were longer and the average costs were higher for the cases

reporting the use of CRRT when compared to all cases in their respective MS–DRG. We note that the claims data demonstrate that the MS–DRG with the largest number of cases reporting CRRT is MS–DRG 871 with 2,912 cases. Of the top 10 MS–DRGs reporting CRRT, the MS–DRG with the smallest number of cases is MS–DRG 682 with 401 cases. The average length of stay of this subset of cases ranges from a high of 35.5 days in MS–DRG 004 to a low of 7.9 days in MS–DRG 871 for cases reporting the use of CRRT. The average costs of this subset of cases ranges from a high of $174,085 in MS–DRG 003 to a low of $27,681 in MS–DRG 871 for cases reporting the use of CRRT.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for the top ten MS–DRGs reporting the use of CRRT. Our similar findings are reflected in the following table:

BILLING CODE 4120–01–P

Top 10 MS-DRGs Reporting Continuous Renal Replacement Therapy

MS-DRG	Description		Number of Cases	Average Length of Stay	Average Costs
	Respiratory System Diagnosis with Ventilator Support >96 Hours	Cases with CRRT	458	16.8	$61,632
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	All cases	15,597	10.9	$57,845
		Cases with CRRT	442	17.1	$98,802
270	Other Major Cardiovascular Procedures with MCC	All cases	18,959	9.5	$37,249
		Cases with CRRT	430	14.8	$70,030
682	Renal Failure with MCC	All cases	103,511	5.7	$10,486
		Cases with CRRT	401	9.8	$29,089

Top 10 MS-DRGs Reporting Continuous Renal Replacement Therapy					
MS-DRG	**Description**		**Number of Cases**	**Average Length of Stay**	**Average Costs**
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC	All cases	552,641	6.4	$14,140
		Cases with CRRT	3,023	7.9	$29,248
870	Septicemia Or Severe Sepsis with MV >96 Hours	All cases	40,079	15.2	$48,909
		Cases with CRRT	2,480	16.7	$66,120
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC	All cases	78,586	12.3	$35,594
		Cases with CRRT	1,464	17.1	$71,270
003	ECMO or Tracheostomy with MV >96 hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures	All cases	11,768	30.9	$137,021
		Cases with CRRT	1,338	34	$182,952
207	Respiratory System Diagnosis with Ventilator Support >96 Hours	All cases	24,106	15.8	$47,379
		Cases with CRRT	976	18.7	$68,254
004	Tracheostomy with MV >96 hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures	All cases	12,248	26.4	$88,922
		Cases with CRRT	600	34.9	$134,323
291	Heart Failure and Shock with MCC	All cases	313,097	5.1	$10,055
		Cases with CRRT	594	10.7	$33,604
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours	All cases	50,397	6.9	$19,519
		Cases with CRRT	496	8.6	$31,853
270	Other Major Cardiovascular Procedures with MCC	All cases	16,764	9.3	$39,520
		Cases with CRRT	416	14.3	$68,957
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	All cases	11,863	10.9	$61,934
		Cases with CRRT	374	18.7	$108,744

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As shown in this table, our data findings show that the average lengths of stay were longer and the average costs were higher for the cases reporting the use of CRRT when compared to all cases in their respective MS–DRG. We noted that the claims data demonstrate that the MS–DRG with the largest number of cases reporting CRRT is MS–DRG 871 with 3,023 cases. Of the top 10 MS–DRGs reporting CRRT, the MS–DRG with the smallest number of cases is MS–DRG 219 with 374 cases. The average length of stay of this subset of cases ranges from a high of 34.9 days in MS–DRG 004 to a low of 7.9 days in MS–DRG 871 for cases reporting the use of CRRT. The average costs of this subset of cases ranges from a high of $182,952 in MS–DRG 003 to a low of $29,248 in MS–DRG 871 for cases reporting the use of CRRT.

We indicated in the proposed rule that, while the results of the claims analysis indicate that the average costs and average lengths of stay for cases reporting the use of CRRT are higher compared to the average costs for all cases in their assigned MS–DRG, we were unable to ascertain from the claims data the resource use specifically attributable to CRRT during a hospital stay. We noted that there is large variability in the differences in average costs from MS–DRG to MS–DRG, indicating there may have been other factors contributing to the higher costs. When reviewing consumption of hospital resources for this subset of cases, the claims data clearly demonstrate the patients typically have a major complication or co-morbid (MCC) condition reported based on the MS–DRGs assigned. The claims data also reflect, based on the top ten MS–DRGS, that the procedure frequently occurs in cases with other procedures with higher than average resource use such as mechanical ventilation, tracheostomy, extracorporeal membrane oxygenation (ECMO) and other major cardiovascular procedures that also may

be contributing to the higher average costs for these cases.

To further examine the variability in cases reporting the use of CRRT, we also reviewed the claims data to identify the number (frequency) and types of principal diagnoses that were reported to determine what factors may also be contributing to the higher average costs for these cases.

Our findings for the top 10 principal diagnoses that were reported within the claims data from the March 2020 update of the FY 2019 MedPAR file for this subset of cases is shown in the following table:

Top 10 Principal Diagnoses Reported with the Procedure Code for Continuous Renal Replacement Therapy

ICD-10-CM Code	Description	Number of Times Reported	Average Length of Stay	Average Costs
A41.9	Sepsis, unspecified organism	4,226	12.6	$48,150
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	691	16.5	$85,557
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	652	20	$81,401
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease	551	17.6	$60,493
A41.51	Sepsis due to Escherichia coli [E. coli]	459	14.7	$54,643
J96.01	Acute respiratory failure with hypoxia	346	13.2	$50,227
N17.9	Acute kidney failure, unspecified	319	13.8	$40,908
N17.0	Acute kidney failure with tubular necrosis	307	14.3	$41,196
A41.59	Other Gram-negative sepsis	273	17.4	$67,917
A41.01	Sepsis due to Methicillin susceptible Staphylococcus aureus	271	17.1	$62,664

The claims data in this table reflects a wide variance with regard to the frequency and types of principal diagnoses that were reported along with the procedure code describing the use of CRRT. We noted that the claims data demonstrate that the diagnosis with the largest number of cases reporting CRRT is A41.9 (Sepsis, unspecified organism) with 4,226 cases. Of the top 10 principal diagnoses reporting CRRT, the diagnosis with the smallest number of cases is A41.01 (Sepsis due to Methicillin susceptible Staphylococcus aureus) with 271 cases. The average length of stay of this subset of cases ranges from a high of 20 days with a diagnosis of I13.0 (Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease) to a low of 12.6 days with a diagnosis of A41.9 (Sepsis, unspecified organism) for cases reporting the use of CRRT. The average costs of this subset of cases ranges from a high of $85,557 with a diagnosis of I21.4 (Non-ST elevation (NSTEMI) myocardial infarction) to a low of $40,908 with a diagnosis of N17.9 (Acute kidney failure, unspecified) for cases reporting the use of CRRT.

Our findings for the top 10 principal diagnoses that were reported within the claims data from the September 2020 update of the FY 2020 MedPAR file for this subset of cases are shown in the following table:

Top 10 Principal Diagnoses Reported with the Procedure Code for Continuous Renal Replacement Therapy				
ICD-10-CM Code	**Description**	**Number of Times Reported**	**Average Length of Stay**	**Average Costs**
A41.9	Sepsis, unspecified organism	4,128	12.5	$51,228
A41.89	Other specified sepsis	1,302	18.8	$76,519
U07.1	COVID-19	868	21.4	$79,721
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	650	16.6	$86,717
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	618	19	$77,404
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease	532	16.3	$59,959
A41.51	Sepsis due to Escherichia coli [E. coli]	437	15.6	$58,858
J96.01	Acute respiratory failure with hypoxia	340	11.8	$48,882
A41.59	Other Gram-negative sepsis	295	16.5	$65,951
N17.0	Acute kidney failure with tubular necrosis	270	16.2	$49,577

The claims data in this table also reflect a wide variance with regard to the frequency and types of principal diagnoses that were reported along with the procedure code describing the use of CRRT. As shown, the claims data demonstrate that the diagnosis with the largest number of cases reporting CRRT is A41.9 (Sepsis, unspecified organism) with 4,128 cases. Of the top 10 principal diagnoses reporting CRRT, the diagnosis with the smallest number of cases is N17.0 (Acute kidney failure with tubular necrosis) with 270 cases. The average length of stay of this subset of cases ranges from a high of 21.4 days with a diagnosis of U07.1 (COVID–19) to a low of 11.8 days with a diagnosis of J96.01 (Acute respiratory failure with hypoxia) for cases reporting the use of CRRT. The average costs of this subset of cases ranges from a high of $86,717 with a diagnosis of I21.4 (Non-ST elevation (NSTEMI) myocardial infarction) to a low of $48,882 with a diagnosis of J96.01 (Acute respiratory failure with hypoxia) for cases reporting the use of CRRT.

As indicated in the proposed rule, to evaluate the frequency with which the use of CRRT is reported for different clinical scenarios, we examined claims from the March 2020 update of the FY 2019 MedPAR file across each of the 25 MDCs to determine the number of cases reporting the use of CRRT. Our findings are shown in this table.

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Continuous Renal Replacement Therapy Across All MDCs			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
All cases with CRRT	19,608	16.5	$68,592
MDC 01 (Diseases and Disorders of the Nervous System)--Cases with CRRT	558	17.5	$64,523
MDC 02 (Disease and Disorders of the Eye)--Cases with CRRT	5	15.4	$36,053
MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)--Cases with CRRT	23	17.4	$65,221
MDC 04 (Diseases and Disorders of the Respiratory System)--Cases with CRRT	1,370	17.8	$72,158
MDC 05 (Diseases and Disorders of the Circulatory System)--Cases with CRRT	6,027	17.9	$86,024
MDC 06 (Diseases and Disorders of the Digestive System)--Cases with CRRT	987	18.8	$73,408
MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas)--Cases with CRRT	870	20.9	$87,272
MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)--Cases with CRRT	412	18.2	$69,621
MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)--Cases with CRRT	72	14.5	$43,633
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)--Cases with CRRT	383	11.8	$41,559
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)--Cases with CRRT	1,134	15.4	$48,276
MDC 12 (Diseases and Disorders of the Male Reproductive System)--Cases with CRRT	9	17.3	$55,931

Continuous Renal Replacement Therapy Across All MDCs			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MDC 13 (Diseases and Disorders of the Female Reproductive System)--Cases with CRRT	15	47.3	$131,252
MDC 14 (Pregnancy, Childbirth and the Puerperium)--Cases with CRRT	3	8	$22,852
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)--Cases with CRRT	134	21.8	$78,138
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)--Cases with CRRT	260	25.8	$95,309
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)--Cases with CRRT	6,761	14.1	$54,051
MDC 19 (Mental Diseases and Disorders)--Cases with CRRT	5	13.8	$30,664
MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders)--Cases with CRRT	5	15.4	$39,332
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)--Cases with CRRT	390	16.3	$61,846
MDC 22 (Burns)--Cases with CRRT	27	19	$104,749
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)--Cases with CRRT	13	15.6	$36,295
MDC 24 (Multiple Significant Trauma)--Cases with CRRT	86	10.2	$59,113
MDC 25 (Human Immunodeficiency Virus Infections)--Cases with CRRT	59	15.6	$50,581

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As shown in the table, the top five MDCs with the largest number of cases reporting CRRT are MDC 18, with 6,761 cases; MDC 05, with 6,027 cases; MDC 04, with 1,370 cases; MDC 11, with 1,134 cases; and MDC 06, with 987 cases. The top five MDCs with the highest average costs for cases reporting the use of CRRT were MDC 13, with average costs of $131,252; MDC 22, with average costs of $104,749; MDC 17, with average costs of $95,309; MDC 07, with average costs of $87,272; and MDC 05, with average costs of $86,024. The claims data indicate that the average length of stay ranges from a high of 47.3 days in MDC 13 to a low of 8 days in MDC 14 for cases reporting the use of CRRT across each of the 25 MDCs.

We also examined claims from the September 2020 update of the FY 2020 MedPAR file across each of the 25 MDCs to determine the number of cases

reporting the use of CRRT. Our findings are shown in this table.

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Continuous Renal Replacement Therapy Across All MDCs			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
All cases with CRRT	20,385	16.5	$70,398
MDC 01 (Diseases and Disorders of the Nervous System)--Cases with CRRT	549	17.6	$67,407
MDC 02 (Disease and Disorders of the Eye)--Cases with CRRT	3	15.7	$50,915
MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)--Cases with CRRT	15	19.1	$68,270
MDC 04 (Diseases and Disorders of the Respiratory System)--Cases with CRRT	2,191	18.4	$71,644
MDC 05 (Diseases and Disorders of the Circulatory System)--Cases with CRRT	5,516	17.4	$87,875
MDC 06 (Diseases and Disorders of the Digestive System)--Cases with CRRT	838	17.2	$71,559
MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas)--Cases with CRRT	803	21.1	$86,894
MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)--Cases with CRRT	357	18.7	$77,515
MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)--Cases with CRRT	73	13.8	$50,455

Continuous Renal Replacement Therapy Across All MDCs			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)--Cases with CRRT	361	12.5	$39,170
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)--Cases with CRRT	1,066	15.9	$54,348
MDC 12 (Diseases and Disorders of the Male Reproductive System)--Cases with CRRT	12	16.8	$59,223
MDC 13 (Diseases and Disorders of the Female Reproductive System)--Cases with CRRT	18	12.8	$45,623
MDC 14 (Pregnancy, Childbirth and the Puerperium)--Cases with CRRT	1	14	$37,193
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)--Cases with CRRT	107	16.4	$63,682
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)--Cases with CRRT	209	21.9	$88,182
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)--Cases with CRRT	7,678	14.7	$59,317
MDC 19 (Mental Diseases and Disorders)--Cases with CRRT	5	18.4	$36,453
MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders)--Cases with CRRT	5	11	$37,345
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)--Cases with CRRT	393	14.7	$61,513
MDC 22 (Burns)--Cases with CRRT	41	26.7	$139,224
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)--Cases with CRRT	8	14.1	$40,364
MDC 24 (Multiple Significant Trauma)--Cases with CRRT	78	14.6	$68,916
MDC 25 (Human Immunodeficiency Virus Infections)--Cases with CRRT	58	16.3	$65,767

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As shown in the table, the top five MDCs with the largest number of cases reporting CRRT are MDC 18, with 7,678 cases; MDC 05, with 5,516 cases; MDC

04, with 2,191 cases; MDC 11, with 1,066 cases; and MDC 06, with 838 cases. The top five MDCs with the highest average costs for cases reporting the use of CRRT were MDC 22, with average costs of $139,244; MDC 17, with average costs of $88,182; MDC 05, with average costs of $87,875; MDC 07, with average costs of $86,894; and MDC 08, with average costs of $ 77,515. The claims data indicate that the average length of stay ranges from a high of 26.7 days in MDC 22 to a low of 11 days in MDC 20 for cases reporting the use of CRRT across each of the 25 MDCs.

We indicated in the proposed rule that our clinical advisors reviewed the clinical issues and the claims data, and did not support creating new MS–DRGs for CRRT without regard to principal diagnosis. Our clinical advisors noted that more than one modality for RRT can be utilized for managing patients with AKI given the needs of the patient. For example, a patient may initially start on CRRT when they are hemodynamically unstable, but transition to IHD as their condition is managed during the admission. While patients requiring CRRT can be more resource intensive, we stated it would not be practical to create new MS–DRGs specifically for this subset of patients given the various clinical presentations for which CRRT may be utilized, and the variation of costs in their assigned MS–DRGs. We further indicated that we believed that additional analysis and efforts toward a broader approach to refining the MS–DRGs for cases of patients requiring renal replacement therapy would be needed to address the concerns expressed by the requestor. These data do show cases reporting the use of CRRT can present greater treatment difficulty. However, when reviewing consumption of hospital resources for this subset of cases, the claims data also suggest that the increased costs may be attributable to the severity of illness of the patient and other circumstances of the admission.

In summary, we indicated in the proposed rule that the claims data reflect a wide variance with regard to the frequency and average costs for cases reporting the use of CRRT. Depending on the number of cases in each MS–DRG, it is difficult to detect patterns of complexity and resource intensity. We indicated we believed the creation of new MS–DRGs for cases with procedure codes reporting the use of CRRT has the potential for creating instability in the relative weights and disrupting the integrity of the MS–DRG system. Therefore, we did not propose to create new MS–DRGs for cases reporting the use of continuous renal replacement therapy.

Comment: A commenter supported CMS' proposal and stated they agreed that new MS–DRGs should not be created for continuous renal replacement therapy without regard to principal diagnosis. Another commenter stated that CMS should group cases reporting the use of continuous renal replacement therapy along with ICD–10–CM diagnosis codes N17.8 (Other acute kidney failure) or N17.9 (Acute kidney failure, unspecified) to the highest (MCC) severity level MS–DRG of its current base MS–DRG assignment. The commenter noted that both N17.8 and N17.9 (Acute kidney failure, unspecified) are designated as a ''CC'' when reported as a secondary diagnosis. This commenter also stated that while CRRT is not a new technology, given its increased costs, CRRT should be considered for a permanent ''add-on'' payment that compensates hospitals for the higher costs of caring for these patients.

Response: We appreciate the commenters' support. With regard to the commenter's statement that cases reporting the use of continuous renal replacement therapy along with ICD–10–CM diagnosis codes N17.8 (Other acute kidney failure) or N17.9 (Acute kidney failure, unspecified) should be grouped to the highest (MCC) severity level MS–DRG of its current base MS–DRG assignment, we consider this comment to be outside the scope of the proposal discussed. We may consider additional claims data analysis for these procedures in future rulemaking. After consideration of the public comments we received, we are finalizing our proposal to not create new MS–DRGs for cases reporting the use of continuous renal replacement therapy for FY 2022.

8. MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunologic Disorders)

a. ANDEXXA® (Coagulation Factor Xa (Recombinant), Inactivated-zhzo)

ANDEXXA® (Coagulation Factor Xa (Recombinant), Inactivated-zhzo) is a recombinant decoy protein that rapidly reverses the anticoagulant effects of two direct oral anticoagulants, apixaban and rivaroxaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding in indications such as intracranial hemorrhages (ICHs) and gastrointestinal bleeds (GIBs). ANDEXXA® received FDA approval on May 3, 2018. When administered as a bolus followed by continuous infusion, ANDEXXA® blocks the anticoagulants ability to inhibit FXa. ANDEXXA® was approved for new technology add on payments in FY 2019 (83 FR 41362). We refer readers to section II.H.5.j. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41355 through 41362), and section II.H.4.k. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42193 through 42194) for a complete discussion of the new technology add on payment application and payment amount for ANDEXXA® for FY 2019 and FY 2020.

In section II.H.4.i. of the preamble of the FY 2021 IPPS/LTCH PPS final rule (85 FR 58614 through 58615), we noted the 3-year anniversary date of the entry of ANDEXXA® onto the U.S. market (May 3, 2021) will occur in the second half of FY 2021. We stated in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. After consideration of the public comments received, we finalized our proposal to continue new technology add-on payments for this technology for FY 2021.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25138 through 25146), we discussed a request we received from the manufacturer to review potential access issues in the inpatient setting for this drug in the future. The requestor acknowledged that CMS approved the new technology add-on payment for ANDEXXA® beginning in FY 2019 and noted that FY 2021 will be the last year before the add-on payments expire. According to the requestor, ANDEXXA® is the only indicated factor Xa inhibitor reversal agent, and the requestor stated a concern for the future of access to ANDEXXA® for patients experiencing uncontrolled bleeds caused by factor Xa inhibitors. The requestor stated their claims modeling showed a significant drop in hospital payment for cases involving use of ANDEXXA® following the expiration of new technology add-on payments. Specifically, after new technology add-on payments expire, the requestor stated their model projects that approximately 59% of cases are likely to be paid less than the wholesale acquisition costs for ANDEXXA®.

We noted in the proposed rule that the following ICD–10–PCS procedure codes identify the intravenous administration of ANDEXXA®.

ICD-10-PCS Code	Code Description
XW03372	Introduction of inactivated coagulation factor Xa into peripheral vein, percutaneous approach, new technology group 2
XW04372	Introduction of inactivated coagulation factor Xa into central vein, percutaneous approach, new technology group 2

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes XW03372 and XW04372 are designated as non-O.R. procedures for purposes of MS–DRG assignment. We indicated that our clinical advisors agreed that the principal diagnosis assigned for inpatient admissions where the intravenous administration of ANDEXXA® is indicated can vary.

To evaluate the frequency with which the intravenous administration of ANDEXXA® is reported for different clinical scenarios in response to this request, we examined claims data from the March 2020 update of the FY 2019 MedPAR file across the Pre-MDC category, each of the 25 MDCs and the surgical class referred to as ''unrelated operating room procedures'' to determine the number of cases reporting the use of ANDEXXA®. Our findings are shown in the following table.

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Cases Reporting ANDEXXA® Therapy			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
All cases reporting XW03372 or XW04372	461	8.7	$42,734
Pre-MDC--Cases reporting XW03372 or XW04372	16	19.9	$107,741
MDC 01 (Diseases and Disorders of the Nervous System)--Cases reporting XW03372 or XW04372	250	7.2	$37,035
MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)--Cases reporting XW03372 or XW04372	2	4	$26,463
MDC 04 (Diseases and Disorders of the Respiratory System)--Cases reporting XW03372 or XW04372	12	5.3	$36,198
MDC 05 (Diseases and Disorders of the Circulatory System)--Cases reporting XW03372 or XW04372	33	16.8	$77,284
MDC 06 (Diseases and Disorders of the Digestive System)--Cases reporting XW03372 or XW04372	53	7.4	$34,485
MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas)--Cases reporting XW03372 or XW04372	2	5	$27,206
MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)--Cases reporting XW03372 or XW04372	14	7.9	$41,082
MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)--Cases reporting XW03372 or XW04372	1	4	$22,242
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)--Cases reporting XW03372 or XW04372	10	7.5	$32,751
MDC 12 (Diseases and Disorders of the Male Reproductive System)--Cases reporting XW03372 or XW04372	1	14	$25,975
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)--Cases reporting XW03372 or XW04372	10	7.4	$40,563
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)--Cases reporting XW03372 or XW04372	3	11.7	$36,541

Cases Reporting ANDEXXA® Therapy			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)--Cases reporting XW03372 or XW04372	25	11.5	$43,355
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)--Cases reporting XW03372 or XW04372	13	6.4	$38,250
MDC 24 (Multiple Significant Trauma)--Cases reporting XW03372 or XW04372	10	10.8	$48,410
MS-DRG 981 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) --Cases reporting XW03372 or XW04372	5	9	$53,775
MS-DRG 987 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) --Cases reporting XW03372 or XW04372	1	12	$31,378

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As shown in the table, there were 461 cases reporting the intravenous administration of ANDEXXA® with procedure codes XW03372 or XW04372. The top five MDCs with the largest number of cases reporting ANDEXXA® are MDC 01, with 250 cases; MDC 06 with 53 cases; MDC 05, with 33 cases; MDC 18, with 25 cases; and the Pre-MDC category, with 16 cases. The claims data indicate that the average costs range from a high of $107,741 in the Pre-MDC category to a low of $22,242 in MDC 09 for cases reporting the use of ANDEXXA® across the claims data. The claims data also indicates that the average length of stay ranges from a high of 19.9 days in the Pre-MDC category to a low of 4 days in MDC 09 for cases reporting the use of ANDEXXA®.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file across the Pre-MDC category, each of the 25 MDCs and the surgical class referred to as ''unrelated operating room procedures'' to determine the number of cases reporting the use of ANDEXXA®. Our findings are shown in the following table.

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Cases Reporting ANDEXXA® Therapy			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
All cases reporting XW03372 or XW04372	719	8.3	$44,393
Pre-MDC--Cases reporting XW03372 or XW04372	28	25	$123,750
MDC 01 (Diseases and Disorders of the Nervous System)--Cases reporting XW03372 or XW04372	364	7.1	$38,841
MDC 04 (Diseases and Disorders of the Respiratory System)--Cases reporting XW03372 or XW04372	13	4.5	$35,988
MDC 05 (Diseases and Disorders of the Circulatory System)--Cases reporting XW03372 or XW04372	50	9.4	$58,583
MDC 06 (Diseases and Disorders of the Digestive System)--Cases reporting XW03372 or XW04372	98	7.8	$39,890
MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas)--Cases reporting XW03372 or XW04372	5	9.2	$31,730
MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)--Cases reporting XW03372 or XW04372	15	7.4	$45,397
MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)--Cases reporting XW03372 or XW04372	9	4.8	$27,922
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)--Cases reporting XW03372 or XW04372	1	8	$33,210
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)--Cases reporting XW03372 or XW04372	9	8.7	$36,565
MDC 12 (Diseases and Disorders of the Male Reproductive System)--Cases reporting XW03372 or XW04372	1	8	$30,119
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)--Cases reporting XW03372 or XW04372	22	5.7	$28,458
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)--Cases reporting XW03372 or XW04372	1	5	$34,819

Cases Reporting ANDEXXA® Therapy			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)--Cases reporting XW03372 or XW04372	52	9.7	$50,963
MDC 19 (Mental Diseases and Disorders)--Cases reporting XW03372 or XW04372	1	15	$37,667
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)--Cases reporting XW03372 or XW04372	9	4.2	$27,987
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)--Cases reporting XW03372 or XW04372	1	7	$28,405
MDC 24 (Multiple Significant Trauma)--Cases reporting XW03372 or XW04372	30	8.4	$41,478
MS-DRG 981 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) --Cases reporting XW03372 or XW04372	9	11.6	$57,895
MS-DRG 987 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) --Cases reporting XW03372 or XW04372	1	5	$34,910

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As shown in the table, there were 719 cases reporting the intravenous administration of ANDEXXA® with procedure codes XW03372 or XW04372. The top five MDCs with the largest number of cases reporting ANDEXXA® are MDC 01, with 364 cases; MDC 06 with 98 cases; MDC 18, with 52 cases; MDC 05, with 50 cases; and MDC 24, with 30 cases. The claims data indicate that the average costs range from a high of $123,750 in the Pre-MDC category to a low of $27,922 in MDC 09 for cases reporting the use of ANDEXXA® across the claims data. The claims data also indicates that the average length of stay ranges from a high of 25 days in the Pre-MDC category to a low of 4.2 days in MDC 21 for cases reporting the use of ANDEXXA® across the claims data.

As discussed in the proposed rule, to further examine the impact of the intravenous administration of ANDEXXA®, we examined claims data from the March 2020 update of the FY 2019 MedPAR file for the top ten MS–DRGs reporting procedure codes XW03372 or XW04372. Our findings are reflected in the following table:

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Top 10 MS-DRGs Reporting ANDEXXA® Therapy					
MS-DRG	**Description**		**Number of Cases**	**Average Length of Stay**	**Average Costs**
064	Intracranial Hemorrhage or Cerebral Infarction with MCC	All cases	77,911	6.1	$13,441
		Cases reporting XW03372 or XW04372	78	6.9	$30,187
023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator	All cases	12,867	9.8	$40,511
		Cases reporting XW03372 or XW04372	27	11	$53,956
086	Traumatic Stupor and Coma <1 Hour with CC	All cases	16,035	3.9	$9,214
		Cases reporting XW03372 or XW04372	25	4.2	$28,603
377	Gastrointestinal Hemorrhage with MCC	All cases	68,798	5.7	$12,897
		Cases reporting XW03372 or XW04372	18	8.6	$35,850
025	Craniotomy and Endovascular Intracranial Procedures with MCC	All cases	21,980	8.8	$31,726
		Cases reporting XW03372 or XW04372	17	9	$55,458
083	Traumatic Stupor and Coma >1 Hour with CC	All cases	10,061	4.3	$9,895
		Cases reporting XW03372 or XW04372	17	4.4	$26,992
082	Traumatic Stupor and Coma >1 Hour with MCC	All cases	6,980	6.4	$16,630
		Cases reporting XW03372 or XW04372	15	7.6	$30,208
085	Traumatic Stupor and Coma <1 Hour with MCC	All cases	8,178	6.5	$16,116
		Cases reporting XW03372 or XW04372	15	6.7	$32,475
065	Intracranial Hemorrhage or Cerebral Infarction with CC or TPA In 24 Hours	All cases	107,737	3.6	$7,375
		Cases reporting XW03372 or XW04372	14	5	$26,992

Top 10 MS-DRGs Reporting ANDEXXA® Therapy					
MS-DRG	**Description**		**Number of Cases**	**Average Length of Stay**	**Average Costs**
003	ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face Mouth and Neck with Major O.R. Procedures	All cases	14,532	30.2	$128,196
		Cases reporting XW03372 or XW04372	13	21.5	$117,265

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As shown in this table, the claims data demonstrate that the MS–DRG with the largest number of cases reporting ANDEXXA® is MS–DRG 064 with 78 cases. Of the top 10 MS–DRGs reporting ANDEXXA®, the MS–DRG with the smallest number of cases is MS–DRG 003 with 13 cases. The average length of stay of this subset of cases ranges from a high of 21.5 days in MS–DRG 003 to a low of 4.2 days in MS–DRG 086 for cases reporting the use of ANDEXXA®. The average costs of this subset of cases ranges from a high of $117,265 in MS–DRG 003 to a low of $26,992 in MS–DRG 083 for cases reporting the use of ANDEXXA®. We noted while our data findings demonstrate the average costs were higher for the cases reporting the intravenous administration of ANDEXXA® when compared to all cases in their respective MS–DRG, these cases represent a very small percentage of the total number of cases reported in these MS–DRGs. We also noted that the top 10 MS–DRGs identified only account for 239 of the 461 cases in total that were identified in the March 2020 update of the FY 2019 MedPAR file reporting ICD–10–PCS codes XW03372 or XW04372. The remainder of the cases are distributed in small numbers across the MS–DRGs.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for the top ten MS–DRGs reporting procedure codes XW03372 or XW04372. Our findings are reflected in the following table:

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Top 10 MS-DRGs Reporting ANDEXXA® Therapy					
MS-DRG	Description		Number of Cases	Average Length of Stay	Average Costs
025	Craniotomy and Endovascular Intracranial Procedures with MCC	All cases	19,643	8.7	$32,933
		Cases reporting XW03372 or XW04372	25	9.3	$59,478
023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator	All cases	12,042	9.7	$42,273
		Cases reporting XW03372 or XW04372	38	10	$58,749
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC	All cases	552,641	6.4	$14,140
		Cases reporting XW03372 or XW04372	26	9	$46,965
377	Gastrointestinal Hemorrhage with MCC	All cases	60,818	5.6	$13,369
		Cases reporting XW03372 or XW04372	36	6.0	$37,949
085	Traumatic Stupor and Coma <1 Hour with MCC	All cases	7,402	6.4	$16,512
		Cases reporting XW03372 or XW04372	29	8.4	$36,530
064	Intracranial Hemorrhage or Cerebral Infarction with MCC	All cases	68,674	6	$13,997
		Cases reporting XW03372 or XW04372	111	6.8	$34,892
083	Traumatic Stupor and Coma >1 Hour with CC	All cases	9,036	4.2	$10,419
		Cases reporting XW03372 or XW04372	23	4.7	$32,678
065	Intracranial Hemorrhage or Cerebral Infarction with CC or TPA In 24 Hours	All cases	86,862	3.5	$7,583
		Cases reporting XW03372 or XW04372	32	5.2	$31,535
086	Traumatic Stupor and Coma <1 Hour with CC	All cases	13,298	3.7	$9,592
		Cases reporting XW03372 or XW04372	41	4.4	$29,221
378	Gastrointestinal Hemorrhage with CC	All cases	101,534	3.5	$7,577
		Cases reporting XW03372 or XW04372	24	3.5	$24,348

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As shown in this table, the claims data demonstrate that the MS–DRG with the largest number of cases reporting ANDEXXA® is MS–DRG 064 with 111 cases. Of the top 10 MS–DRGs reporting ANDEXXA®, the MS–DRG with the smallest number of cases is MS–DRG 083 with 23 cases. The average length of stay of this subset of cases ranges from a high of 10 days in MS–DRG 023 to a low of 3.5 days in MS–DRG 378 for cases reporting the use of ANDEXXA®.

The average costs of this subset of cases ranges from a high of $59,478 in MS–DRG 025 to a low of $24,348 in MS–DRG 378 for cases reporting the use of ANDEXXA®. As with our analysis of the FY 2019 claims data, while these data findings demonstrate the average costs were higher for the cases reporting the intravenous administration of ANDEXXA® when compared to all cases in their respective MS–DRG, these cases represent a very small percentage of the total number of cases reported in these MS–DRGs. We also noted that the top 10 MS–DRGs identified only account for 385 of the 719 cases in total that were identified in the September 2020 update of the FY 2020 MedPAR file reporting ICD–10–PCS codes XW03372 or XW04372. The remainder of the cases are distributed in small numbers across the MS–DRGs.

After reviewing the claims data, we indicated in the proposed rule that we believe it is premature to consider a proposal for cases involving ANDEXXA® therapy for FY 2022. We noted that while the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file do contain claims reporting the procedure codes identifying the intravenous administration of ANDEXXA®, the number of cases is small across the MDCs and MS–DRGs. We also noted the claims data also reflects a wide variance with regard to the frequency and average costs for these cases reporting the use of ANDEXXA®. Moreover, we indicated we were unable to identify another MS–DRG that would be a more appropriate MS–DRG assignment for these cases based on the indication for this therapeutic drug. As noted previously, ANDEXXA® reverses the anticoagulant effects of apixaban and rivaroxaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. The underlying cause of the life-threatening or uncontrolled bleeding can vary which means the principal diagnosis assigned for inpatient admissions where ANDEXXA® is administered can vary. The MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. As discussed in the proposed rule, we generally seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnostic-related groups rather than smaller subsets based on the drugs administered. In reviewing this issue, we indicated our clinical advisors expressed concern regarding making potential MS–DRG changes based on a specific, single therapeutic agent, identified by unique procedure codes rather than based on a group of related procedure codes that can be reported to describe that same type or class of treatment or technology, which is more consistent with the intent of the MS–DRGs.

We indicated that we recognized that the average costs of the small numbers of cases involving the intravenous administration of ANDEXXA® are greater when compared to the average costs of all cases in their respective MS–DRG. We noted that the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We further noted that section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs.

In the proposed rule, we acknowledged the importance of ensuring that patients diagnosed with an indication for a factor Xa inhibitor reversal agent have adequate access to care and receive the necessary treatment. While we are sensitive to the requestors' concerns about continued access to treatment for beneficiaries who require the reversal of anticoagulation due to life-threatening or uncontrolled bleeding, we indicated additional time is needed to explore options and other mechanisms through which to address low volume high-cost drugs outside of the MS–DRGs.

Furthermore, we noted that we were proposing to continue new technology add-on payments for ANDEXXA® for FY 2022. We refer the reader to section II.F.4.b of the preamble of the proposed rule and this final rule for further discussion regarding our proposal to allow a one-time extension of new technology add-on payments for FY 2022 for 15 technologies for which the new technology add-on payment would otherwise be discontinued, in connection with our proposal to use the FY 2019 data to develop the proposed FY 2022 relative weights, as well as our finalization of that proposal.

Therefore, for the reasons stated previously, for FY 2022 we did not propose any MS–DRG changes for cases involving the intravenous administration of ANDEXXA®.

Comment: Commenters expressed appreciation for the consideration CMS provided. These commenters acknowledged that ANDEXXA® presents a unique challenge because MS–DRGs are a classification system for grouping diagnoses and procedures with similar clinical characteristics and utilization of resources. Another commenter agreed that the underlying cause of life-threatening or uncontrolled bleeding can vary and stated that cases involving the use of ANDEXXA® (coagulation factor Xa (recombinant), inactivated-zhzo) do not fit neatly within another MS–DRG. These commenters also agreed that options and mechanisms through which to address low volume high-cost drugs should be explored outside of the MS–DRG classification.

Response: We appreciate the commenters' support, and intend to continue to consider these issues. For the reasons summarized earlier, and after consideration of the public comments we received, we are not making any MS–DRG changes for cases involving the intravenous administration of ANDEXXA® for FY 2022.

b. Cytokine Release Syndrome (CRS) Logic

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58557 through 58561), we finalized modifications to the proposed severity level designations for a subset of the diagnosis codes describing Cytokine Release Syndrome (CRS) based upon further review of the conditions and in response to public comments. We provided the following table to display the finalized severity level designations and stated that we will continue to monitor the CRS codes and their impact on resource use once the claims data become available to determine if further modifications to the severity level are warranted.

ICD-10-CM Code	Description	Proposed Severity Level	Finalized Severity Level
D89.83l	Cytokine release syndrome, grade 1	NonCC	NonCC
D89.832	Cytokine release syndrome, grade 2	NonCC	NonCC
D89.833	Cytokine release syndrome, grade 3	NonCC	CC
D89.834	Cytokine release syndrome, grade 4	NonCC	CC
D89.835	Cytokine release syndrome, grade 5	NonCC	CC
D89.839	Cytokine release syndrome, grade unspecified	NonCC	NonCC

In connection with the finalized severity level designations for the listed CRS codes, we also finalized modifications to the ICD–10 MS–DRG GROUPER logic V38 for MS–DRGs 814, 815, and 816 (Reticuloendothelial and Immunity Disorders with MCC, with CC, and without CC/MCC, respectively) to conform to the updates the CDC finalized in the ICD–10–CM Tabular List instructions for assigning and reporting the CRS codes effective with discharges on and after October 1, 2020. The following modifications to the GROUPER logic were finalized effective with discharges on and after October 1, 2020, for case assignment involving CRS following CAR T-cell therapy to MS–DRGs 814, 815, and 816. We noted that the GROUPER logic for MS–DRGs 814, 815, and 816 will include a principal diagnosis of T80.89XA with a secondary diagnosis of any CRS code as shown.

Principal Diagnosis
- T80.89XA Other complications following infusion, transfusion and therapeutic injection, initial encounter

with

Secondary Diagnosis
- D89.831 Cytokine release syndrome, grade 1
- D89.832 Cytokine release syndrome, grade 2
- D89.833 Cytokine release syndrome, grade 3
- D89.834 Cytokine release syndrome, grade 4
- D89.835 Cytokine release syndrome, grade 5
- D89.839 Cytokine release syndrome, grade unspecified

As discussed in section II.D.13 of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date and will be effective with discharges on and after October 1, 2021. Included in Table 6A are the following codes that describe complication of immune effector cellular therapy identifying the timeframe of the encounter.

ICD-10-CM Code	Description
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XD	Complication of immune effector cellular therapy, subsequent encounter
T80.82XS	Complication of immune effector cellular therapy, sequela

Also included in Table 6A are the following diagnosis codes that describe immune effector cell-associated neurotoxicity syndrome (ICANS), with varying degrees of severity.

ICD-10-CM Code	Description
G92.00	Immune effector cell-associated neurotoxicity syndrome, grade unspecified
G92.01	Immune effector cell-associated neurotoxicity syndrome, grade 1
G92.02	Immune effector cell-associated neurotoxicity syndrome, grade 2
G92.03	Immune effector cell-associated neurotoxicity syndrome, grade 3
G92.04	Immune effector cell-associated neurotoxicity syndrome, grade 4
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5

Consistent with the Tabular List instruction for these two sets of diagnosis codes as presented and discussed by the CDC at the September 8–9, 2020 ICD–10 Coordination and Maintenance Committee meeting, the diagnosis codes describing a complication of the immune effector cellular therapy (T80.82XA, T80.82XD, and T80.82XS) are to be sequenced first, followed by the applicable diagnosis code to identify the specified condition resulting from the complication. For example, the types of complications that may result from immune effector

cellular therapy treatment (for example, CAR T-cell therapy) include ICANS or CRS, as described by the listed diagnosis codes. Accordingly, the CDC included the following instructional note in the Tabular List modifications for code T80.82—

''Use additional code to identify the specific complication, such as: cytokine release syndrome (D89.83–) immune effector cell-associated neurotoxicity syndrome (G92.0–)''

Materials relating to the discussions involving the diagnosis codes from the September 8–9, 2020 ICD–10 Coordination and Maintenance Committee meeting can be obtained from the CDC website at: *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm*.

As noted previously, the current logic for case assignment involving CRS following CAR T-cell therapy to MS–DRGs 814, 815, and 816 includes a principal diagnosis of T80.89XA with a secondary diagnosis of any CRS code. However, with the finalization of new diagnosis code T80.82–, diagnosis code T80.89XA would no longer be reported and these cases would instead report new diagnosis code T80.82XA, effective with discharges on and after October 1, 2021. As shown in Table 6A associated with the proposed rule, we proposed to assign diagnosis code T80.82XA to MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, and Immunologic Disorders) in MS–DRGs 814, 815, and 816. We stated that if the MDC and MS–DRG assignment for new diagnosis code T80.82XA is finalized, the current logic for MS–DRGs 814, 815, and 816 that includes a principal diagnosis code of T80.89XA with a secondary diagnosis code of any CRS code would no longer be appropriate or necessary.

Therefore, we proposed to revise the structure of MS–DRGs 814, 815, and 816 by removing the logic that includes a principal diagnosis of T80.89XA with a secondary diagnosis of any CRS code from MS–DRGs 814, 815, and 816 effective FY 2022.

Comment: Commenters supported the proposed revision to the structure of MS–DRGs 814, 815, and 816 to remove the logic that includes a principal diagnosis of T80.89XA with a secondary diagnosis of any CRS code from MS–DRGs 814, 815, and 816. Commenters also supported the proposed assignment of new diagnosis code T80.82XA to MS–DRGs 814, 815, and 816 in MDC 16.

Response: We appreciate the commenters' support.

Comment: A commenter requested that CMS explain its rationale for MS–DRG assignment of the listed diagnosis codes describing complication of immune effector cellular therapy (T80.82XA, T80.82XD, and T80.82XS) and the codes describing immune effector cell-associated neurotoxicity syndrome (ICANS), with varying degrees of severity (G92.00, G92.01, G92.02, G92.03, G92.04, and G92.05). Specifically, the commenter questioned why CMS limited assignment to these MS–DRGs and if consideration could be given for the codes to be identified as CCs or MCCs for any MS–DRG.

Response: As discussed in prior rulemaking and in the proposed rule (86 FR 25186), we use our established process which involves examining the MS–DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our proposed assignments and designations. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We note that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same MS–DRG or to have the same designation as the predecessor code. We encourage the commenter to also review the FY 2022 Conversion Table that was made publicly available via the internet on the CDC website at: *https://www.cdc.gov/nchs/icd/icd10cm.htm*, the V38.1 ICD–10 MS–DRG Definitions Manual that is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*, and Table 6A.—New Diagnosis Codes associated with the proposed and final rules (available via the internet on the CMS website at: *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-proposed-rule-home-page#Tables*) for information regarding MDC, MS–DRG and severity level assignment for these diagnosis codes. As shown in the Conversion Table, the predecessor code for new diagnosis code T80.82XA is diagnosis code T80.89XA; as shown in Appendix B—Diagnosis Code/MDC/MS–DRG Index of the V38.1 ICD–10 MS–DRG Definitions Manual, diagnosis code T80.89XA is assigned to MDC 16 in MS–DRGs 814–816; and as shown in Table 6A.- New Diagnosis Codes, the finalized severity level assignments for the diagnosis codes inquired about are as follows:

ICD-10-CM Code	Description	Severity Level
G92.00	Immune effector cell-associated neurotoxicity syndrome, grade unspecified	N
G92.01	Immune effector cell-associated neurotoxicity syndrome, grade 1	N
G92.02	Immune effector cell-associated neurotoxicity syndrome, grade 2	N
G92.03	Immune effector cell-associated neurotoxicity syndrome, grade 3	C
G92.04	Immune effector cell-associated neurotoxicity syndrome, grade 4	C
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5	C
T80.82XA	Complication of immune effector cellular therapy, initial encounter	N
T80.82XD	Complication of immune effector cellular therapy, subsequent encounter	N
T80.82XS	Complication of immune effector cellular therapy, sequela	N

Effective October 1, 2021, when diagnosis code G92.03, G92.04 or G92.05 are reported as a secondary diagnosis, the GROUPER logic would recognize any one of these codes as a CC and the appropriate ''with CC'' MS–DRG would be assigned.

After consideration of the public comments we received, we are finalizing our proposal to assign diagnosis code T80.82XA to MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, and Immunologic Disorders) in MS–DRGs 814, 815, and 816. We are also finalizing our proposal to revise the structure of MS–DRGs 814, 815, and 816 by removing the logic that includes a principal diagnosis of T80.89XA with a secondary diagnosis of any CRS code from MS–DRGs 814, 815, and 816 effective FY 2022.

9. MDC 17 (Myeloproliferative Diseases and Disorders, and Poorly Differentiated Neoplasms): Inferior Vena Cava Filter Procedures

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58517 through 58520), we discussed the ICD–10–PCS codes that describe the insertion of an intraluminal device into the inferior vena cava that are listed in the following table.

ICD-10-PCS Code	Code Description
06H003T	Insertion of infusion device, via umbilical vein, into inferior vena cava, open approach
06H003Z	Insertion of infusion device, into inferior vena cava, open approach
06H00DZ	Insertion of intraluminal device, into inferior vena cava, open approach
06H033T	Insertion of infusion device, via umbilical vein, into inferior vena cava, percutaneous approach
06H033Z	Insertion of infusion device, into inferior vena cava, percutaneous approach
06H03DZ	Insertion of intraluminal device, into inferior vena cava, percutaneous approach
06H043Z	Insertion of infusion device, into inferior vena cava, percutaneous endoscopic approach
06H04DZ	Insertion of intraluminal device, into inferior vena cava, percutaneous endoscopic approach

We finalized a change in the designation of ICD–10–PCS procedure code 06H03DZ from O.R. procedure to non-O.R. procedure and maintained the O.R. designation of procedure codes 06H00DZ and 06H04DZ. In that discussion, we noted our clinical advisors supported changing the O.R. designation of procedures describing insertion of an intraluminal device into the inferior vena cava performed via a percutaneous approach since the procedure does not require the resources of an operating room, while concurring that procedures describing the insertion of an intraluminal device into the inferior vena cava performed via an open or a percutaneous endoscopic approach could require greater resources than a procedure describing insertion of an intraluminal device into the inferior vena cava performed via a percutaneous approach. We also noted that the goals of changing the designation of procedures from non-O.R. to O.R., or vice versa, are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system and not whether the change in designation would impact payment in a particular direction.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25147 through 25149), we discussed a request we received to revise MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with and without CC/MCC, respectively) by removing the current two-way severity level split and creating a three-way severity level split in response to this final policy. The requestor respectfully disagreed with the FY 2021 IPPS/LTCH PPS final rule decision to change the designation of the procedure code describing the insertion of an inferior vena cava intraluminal device via percutaneous approach to a non-O.R. procedure, and stated vena cava filters are most often placed in interventional radiology suites and require a high level of skill to prevent rupture of the vena cava; and although they are long-term devices, they must be placed skillfully to allow for removal later if needed.

According to the requestor, it is a conundrum that patients with principal and secondary diagnoses that qualify for medical MS–DRGs 837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC), MS–DRG 838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent), and MS–DRG 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis without CC/MCC) group to lower weighted surgical MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with and without CC/MCC, respectively) when a non-major O.R. procedure is performed. The requestor stated the difference in relative weights might be occurring because of the two-way split within MS–DRGs 829 and 830 and the three-way split within MS–DRGs 837, 838 and 839. The requestor theorized that removing the current two-way severity level split of MS–DRGs 829 and 830 and creating a three-way severity level split could help resolve the relative weight discrepancy when any non-major O.R. procedures are performed during hospitalizations for chemotherapy for acute leukemia.

This requestor also suggested that if CMS' analysis did not support creating a three-way split for MS–DRGs 829 and 830, exclusion of PCS code 06H03DZ from the list of qualifying procedures and reinstatement of O.R. procedure status to appropriately compensate providers for the cost of devices and

resources to place inferior vena cava filters across the patient population should be proposed.

As indicated in the proposed rule, to evaluate the request to create a three-way severity split MS–DRG for cases reporting myeloproliferative disorders or poorly differentiated neoplasms with other procedures, consistent with our established process, we conducted an analysis of base MS–DRG 829. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported.

Therefore, we reviewed the claims data for base MS–DRG 829 using the September 2018 update of the FY 2018 MedPAR file and the March 2020 update of the FY 2019 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2020 and FY 2022, respectively. Our findings are shown in the table:

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases NonCC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs NonCC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2019	2,099	686	1,080	333	$21,657	$35,618	$16,103	$10,909	$23,684	$14,879
2018	2,116	668	1,115	333	$20,355	$33,693	$15,513	$9,811	$22,324	$14,202

We applied the criteria to create subgroups for the three-way severity level split. We found that the criterion that there be at least 500 cases for each subgroup was not met based on the data in both the FY 2018 and FY 2019 MedPAR files, as shown in the table for both years. Specifically, for the ''with MCC'', ''with CC'', and ''without CC/MCC'' split, there were only 333 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2019 MedPAR file and only 333 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2018 MedPAR file. Accordingly, the claims data do not support a three-way severity level split for base MS–DRG 829.

We also reviewed the claims data for base MS–DRG 829 using the September 2019 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2021 and FY 2022, respectively. Our findings are shown in the table:

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases NonCC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs NonCC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2020	1,993	647	1,043	303	$20,494	$31,734	$16,220	$11,204	$22,159	$15,091
2019	2,099	686	1,080	333	$21,657	$35,618	$16,103	$10,909	$23,684	$14,879

We applied the criteria to create subgroups for the three-way severity level split. We found that the criterion that there be at least 500 cases for each subgroup was not met based on the data in both the FY 2019 and FY 2020 MedPAR files, as shown in the table for both years. Specifically, for the ''with MCC'', ''with CC'', and ''without CC/MCC'' split, there were only 303 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2020 MedPAR file and, as previously noted, only 333 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2019 MedPAR file. As shown in both sets of data and stated previously, the claims data do not support a three-way severity level split for base MS–DRG 829.

As discussed in the proposed rule, in response to the request to exclude ICD–10–PCS code 06H03DZ from a list of qualifying procedures if CMS' analysis did not support creating a three-way split for MS–DRGs 829 and 830, we noted that by definition, procedure codes designated as non-O.R. procedures, not further classified as ''affecting the MS–DRG assignment'', do not influence the MS–DRG assignment. As stated previously, in the FY 2021 IPPS/LTCH PPS final rule we finalized our proposal to change the designation of ICD–10–PCS procedure code 06H03DZ from O.R. procedure to non-O.R. procedure, therefore as a non-O.R. procedure, there is no need to exclude ICD–10–PCS code 06H03DZ from a list of qualifying procedure codes for MS–DRGs 829 and 830.

In response to the request to reinstate the O.R. procedure designation of ICD–10–PCS code 06H03DZ if CMS' analysis did not support creating a three-way split for MS–DRGs 829 and 830, we indicated the change in designation from O.R. procedure to non-O.R. procedure was recent, only becoming effective October 1, 2020. We indicated our clinical advisors continued to indicate that code 06H03DZ, describing the percutaneous insertion of an intraluminal device into the inferior vena cava, does not require the resources of an operating room, that the procedure to insert an IVC filter percutaneously is not surgical in nature and that the resources involved in furnishing this procedure are comparable to the related ICD–10–PCS procedure codes that describe the insertion of infusion devices into the inferior vena cava that are currently designated as non-O.R. procedures. We noted our clinical advisors stated that our FY 2021 final policy resulted in an O.R. designation of 06H03DZ that better reflects the associated technical complexity and hospital resource use of this procedure. We also noted that we continue to explore alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data, as discussed in the FY 2021 IPPS/LTCH PPS final rule and in section II.D.11. of the preamble of the proposed rule and this final rule. We indicated we continue to develop our process and methodology, and that we will provide more detail in future rulemaking.

In summary, based on the results of our analysis, for FY 2022, we proposed to maintain the current structure of MS–DRGs 829 and 830.

Comment: Commenters expressed support for CMS' proposal to maintain the current structure of MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with and without CC/MCC, respectively) and not create a three-way severity level split.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current structure of MS–DRGs 829 and 830, without modification, for FY 2022.

10. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

In addition to this internal review, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS DRGs to which the procedure codes are assigned.

Based on the results of our review of the claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, as well as our review of the requests that we received to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we proposed to move the cases reporting the procedures and/or principal diagnosis codes described in this section of this rule from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

As discussed in section II.D.3.b. of the preamble of the proposed rule and this final rule, we received a request to reassign cases with procedures describing control of bleeding in the cranial cavity when reported with a central nervous system diagnosis from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MDC 01 (Diseases and Disorders of the Central Nervous System) in MS–DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively (for example, ''craniotomy'' MS–DRGs). We noted that in addition to MS–DRGs 25, 26, and 27, MS–DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) and MS–DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) also include procedures performed on structures located within the cranial cavity and are included in the range of MS–DRGs known as the ''craniotomy'' MS–DRGs in MDC 01.

The management and treatment for bleeding (or hemorrhage) within the cranial cavity varies depending on the location, cause and the severity (or extent) of the bleed. Common causes include head trauma or cerebral aneurysm. Control of bleeding in the cranial cavity procedures are identified by ICD–10–PCS procedure codes 0W310ZZ (Control bleeding in cranial cavity, open approach), 0W313ZZ (Control bleeding in cranial cavity, percutaneous approach) and 0W314ZZ (Control bleeding in cranial cavity, percutaneous endoscopic approach) and are currently assigned to the following MDCs and MS–DRGs.

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MDC	Description	MS-DRG	Description
03	Diseases and Disorders of the Ear, Nose, Mouth and Throat	143	Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC
		144	Other Ear, Nose, Mouth and Throat O.R. Procedures with CC
		145	Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC
05	Diseases and Disorders of the Circulatory System	264	Other Circulatory System O.R. Procedures
10	Endocrine, Nutritional and Metabolic Diseases and Disorders	628	Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC
		629	Other Endocrine, Nutritional and Metabolic O.R. Procedures with CC
		630	Other Endocrine, Nutritional and Metabolic O.R. Procedures without CC/MCC
17	Myeloproliferative Diseases and Disorders, and Poorly Differentiated Neoplasms	820	Lymphoma and Leukemia with Major O.R. Procedures with MCC
		821	Lymphoma and Leukemia with Major O.R. Procedures with CC
		822	Lymphoma and Leukemia with Major O.R. Procedures without CC/MCC
		826	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC
		827	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with CC
		828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures without CC/MCC
21	Injuries, Poisonings and Toxic Effects of Drugs	907	Other O.R. Procedures for Injuries with MCC
		908	Other O.R. Procedures for Injuries with CC
		909	Other O.R. Procedures for Injuries without CC/MCC
24	Multiple Significant Trauma	957	Other O.R. Procedures for Multiple Significant Trauma with MCC
		958	Other O.R. Procedures for Multiple Significant Trauma with CC
		959	Other O.R. Procedures for Multiple Significant Trauma without CC/MCC

24	Multiple Significant Trauma	957	Other O.R. Procedures for Multiple Significant Trauma with MCC
		958	Other O.R. Procedures for Multiple Significant Trauma with CC
		959	Other O.R. Procedures for Multiple Significant Trauma without CC/MCC

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According to the requestor, procedures performed within the cranial cavity always involve drilling or cutting through the skull regardless of the approach, therefore the three procedure codes identified (0W310ZZ, 0W313ZZ, and 0W314ZZ) warrant assignment to the ''craniotomy'' MS–DRGs.

We stated in the proposed rule that our analysis of this grouping issue confirmed that when a procedure describing control of bleeding in the cranial cavity is reported with a principal diagnosis from MDC 01, these cases group to MS–DRGs 981, 982, and 983. Whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

As noted in the proposed rule, we examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting any one of the three procedure codes (0W310ZZ, 0W313ZZ or 0W314ZZ) in MS–DRGs 981 through 983 with a principal diagnosis from MDC 01. Our findings are shown in the following tables.

MS-DRGs 981-983: Cases Reporting Procedures Describing Control of Bleeding in Cranial Cavity with a Principal Diagnosis from MDC 01 – FY 2019

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
981 - All cases	26,451	11.7	$32,022
981 - Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	8	9.8	$30,843
982 - All cases	13,853	6.2	$18,176
982 - Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	1	9.0	$51,234
983- All cases	2,652	3.0	$12,163
983 - Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	1	4.0	$14,934

MS-DRGs 981-983: Cases Reporting Procedures Describing Control of Bleeding in Cranial Cavity with a Principal Diagnosis from MDC 01 – FY 2020			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
981 - All cases	22,819	11.5	$33,620
981 - Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	1	18.0	$38,565
982 - All cases	11,052	6.0	$18,608
983 - All cases	2,003	2.7	$13,396
983 - Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	1	4.0	$9,152

As noted previously, the requestor asked that we consider reassignment of these cases to the craniotomy MS–DRGs (identified as MS–DRGs 23, 24, 25, 26, and 27). We therefore examined the data for all cases in MS–DRGs 23, 24, 25, 26, and 27. Our findings are shown in the following tables.

MS-DRGs 23 through 27: All Cases – FY 2019			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
23 - All cases	12,867	9.8	$40,511
24 - All cases	4,624	5.2	$28,583
25 - All cases	21,980	8.8	$31,726
26 - All cases	9,547	5.3	$22,347
27 - All cases	10,495	2.5	$18,574

MS-DRGs 23 through 27: All Cases – FY 2020			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
23 - All cases	12,042	9.7	$42,273
24 - All cases	4,087	5.1	$30,278
25 - All cases	19,643	8.7	$32,933
26 - All cases	7,609	5.2	$23,226
27 - All cases	7,866	2.4	$19,427

As shown, in our analyses of the claims data for MS–DRGs 981 through 983, we found a total of ten cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01 in the March 2020 update of the FY 2019 MedPAR file, and a total of two cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01 in the September 2020 update of the FY 2020 MedPAR file.

As noted in the proposed rule, our clinical advisors stated these procedures

describing control of bleeding in the cranial cavity are consistent with the existing procedure codes included in the logic for case assignment to MS–DRGs 25, 26, and 27, in addition to MS–DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) and MS–DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) that also describe procedures performed on structures located within the cranial cavity and are included in the range of MS–DRGs known as the ''craniotomy'' MS–DRGs. While the claims analysis based on the March 2020 update of the FY 2019 MedPAR file identified only ten cases and the September 2020 update of the FY 2020 MedPAR file identified only two cases for which these procedures were reported as a stand-alone procedure resulting in assignment to MS–DRGs 981 through 983, and the average length of stay and average costs for these cases vary in comparison to the average length of stay and average costs of all cases in MS–DRGs 23, 24, 25, 26, and 27, given the nature of head trauma cases, the resource use would be expected to vary based on the extent of the patient's injuries. We stated in the proposed rule that we believed it is clinically appropriate to add these procedure codes describing control of bleeding in the cranial cavity to MS–DRGs 23, 24, 25, 26, and 27 in MDC 01.

Therefore, we proposed to add procedure codes 0W310ZZ, 0W313ZZ, and 0W314ZZ to MDC 01 in MS–DRGs 23, 24, 25, 26, and 27 (''craniotomy'' MS–DRGs) for FY 2022.

Comment: Commenters agreed with our proposal to add procedure codes 0W310ZZ, 0W313ZZ, and 0W314ZZ to MDC 01 in MS–DRGs 23, 24, 25, 26, and 27.

Response: We thank the commenters for their support.

After consideration of the public comments received, we are finalizing our proposal to add procedure codes 0W310ZZ, 0W313ZZ, and 0W314ZZ describing bleeding in the cranial cavity to MDC 01 in MS–DRGs 23, 24, 25, 26, and 27 for FY 2022.

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those two groups of MS–DRGs to the other group of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner.

In addition to this internal review, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate for the cases to be reassigned from one of the MS–DRG groups to the other.

Based on the results of our review of the claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, as well as our review of the requests that we received to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we proposed to move the cases reporting the procedures codes described in this section of this rule from MS–DRGs 981 through 983 to MS–DRGs 987 through 989.

As discussed in section II.D.3.a. of the preamble of the proposed rule and this final rule, we received a request that we understood to be for our consideration of the reassignment of the following three procedure codes from Extensive O.R. procedures to Non-extensive O.R. procedures.

ICD-10-PCS Code	Description
0JB60ZZ	Excision of chest subcutaneous tissue and fascia, open approach
0JB70ZZ	Excision of back subcutaneous tissue and fascia, open approach
0JB80ZZ	Excision of abdomen subcutaneous tissue and fascia, open approach

As stated in the proposed rule, in conducting our review of this request, our clinical advisors noted that ICD–10–PCS codes 0JB60ZZ, 0JB70ZZ, and 0JB80ZZ currently group to MS–DRGs 981 through 983 when reported with a principal diagnosis that is not assigned to one of the MDCs to which these procedure codes are assigned. While our claims analysis of both the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file did not identify any cases reporting any one of the three listed procedure codes in MS–DRGs 981, 982, or 983, we stated that our clinical advisors believe that these procedures would be more appropriately designated as Non-extensive procedures because they are more consistent with other procedures on the Non-extensive procedure code list. They stated that these procedures do not consume the resources or require a similar level of technical complexity as the procedures on the Extensive O.R. procedures list.

Therefore, we proposed to reassign the three procedure codes listed from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively) for FY 2022.

Comment: Commenters supported our proposal to reassign procedure codes 0JB60ZZ, 0JB70ZZ, and 0JB80ZZ from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to reassign procedure codes 0JB60ZZ, 0JB70ZZ, and 0JB80ZZ describing excision of subcutaneous tissue from the chest, back, and abdomen, respectively, from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989 for FY 2022.

As discussed in section II.D.4.b. of the preamble of the proposed rule and this final rule, we identified 17 procedure codes describing laser interstitial thermal therapy (LITT) that are currently designated as extensive O.R. procedures. In addition to those 17 procedure codes, we identified additional procedure codes describing LITT of various body parts that are also designated as extensive O.R. procedures. The ICD–10–PCS codes describing LITT of various body parts are as follows.

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ICD-10-PCS Code	Description
D0Y0KZZ	Laser interstitial thermal therapy of brain
D0Y1KZZ	Laser interstitial thermal therapy of brain stem
D0Y6KZZ	Laser interstitial thermal therapy of spinal cord
D0Y7KZZ	Laser interstitial thermal therapy of peripheral nerve
DBY0KZZ	Laser interstitial thermal therapy of trachea
DBY1KZZ	Laser interstitial thermal therapy of bronchus
DBY2KZZ	Laser interstitial thermal therapy of lung
DBY5KZZ	Laser interstitial thermal therapy of pleura
DBY6KZZ	Laser interstitial thermal therapy of mediastinum
DBY7KZZ	Laser interstitial thermal therapy of chest wall
DBY8KZZ	Laser interstitial thermal therapy of diaphragm
DDY0KZZ	Laser interstitial thermal therapy of esophagus
DDY1KZZ	Laser interstitial thermal therapy of stomach
DDY2KZZ	Laser interstitial thermal therapy of duodenum
DDY3KZZ	Laser interstitial thermal therapy of jejunum
DDY4KZZ	Laser interstitial thermal therapy of ileum
DDY5KZZ	Laser interstitial thermal therapy of colon
DDY7KZZ	Laser interstitial thermal therapy of rectum
DDY8KZZ	Laser interstitial thermal therapy of anus
DFY0KZZ	Laser interstitial thermal therapy of liver
DFY1KZZ	Laser interstitial thermal therapy of gallbladder
DFY2KZZ	Laser interstitial thermal therapy of bile ducts
DFY3KZZ	Laser interstitial thermal therapy of pancreas
DGY0KZZ	Laser interstitial thermal therapy of pituitary gland
DGY1KZZ	Laser interstitial thermal therapy of pineal body
DGY2KZZ	Laser interstitial thermal therapy of adrenal glands
DGY4KZZ	Laser interstitial thermal therapy of parathyroid glands
DGY5KZZ	Laser interstitial thermal therapy of thyroid
DMY0KZZ	Laser interstitial thermal therapy of left breast
DMY1KZZ	Laser interstitial thermal therapy of right breast
DVY0KZZ	Laser interstitial thermal therapy of prostate

BILLING CODE 4210–01–C

Whenever one of these listed procedure codes is reported on a claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it currently results in assignment to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Our clinical advisors stated that all of the listed procedure codes warrant redesignation from the extensive procedure list and MS–DRGs 981, 982, and 983 to the non-extensive procedure list and to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Specifically, our clinical advisors stated the procedures described by these codes are minimally invasive and are consistent with other ablation (root operation Destruction) type procedures that are designated as non-extensive procedures in the ICD–10–PCS classification.

As noted in the proposed rule, in our analysis of claims from the March 2020 update of the FY 2019 MedPAR file, we identified a total of six cases reporting procedure codes describing LITT of various body sites in MS–DRGs 981, 982, and 983 with an average length of stay of 2.5 days and average costs of $7,734. Specifically, we found one case reporting procedure code DVY0KZZ (Laser interstitial thermal therapy of prostate) in MS–DRG 981 with an average length of stay of 4.0 days and average costs of $7,348. For MS–DRG 982, we found five cases in which procedure codes describing LITT of various body sites were reported. The first case reported procedure code D0Y0KZZ (Laser interstitial thermal therapy of brain) with an average length of stay of 1.0 day and average costs of $4,142, the second case reported procedure code D0Y6KZZ (Laser interstitial thermal therapy of spinal cord) with an average length of stay of 3.0 days and average costs of $20,007, the third case reported procedure code DDY1KZZ (Laser interstitial thermal therapy of stomach) with an average length of stay of 2.0 days and average

costs of $3,424, the fourth case reported procedure code DDY7KZZ (Laser interstitial thermal therapy of rectum) with an average length of stay of 3.0 days and average costs of $3,735, and the fifth case reported procedure code DVY0KZZ (Laser interstitial thermal therapy of prostate) with an average length of stay of 2.0 days and average costs of $7,750. There were no cases found to report procedures describing LITT in MS–DRG 983. Our findings are summarized in the following table.

MS-DRGs 981-983: Cases Reporting Procedures Describing LITT – FY 2019

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
981 - All cases	26,451	11.7	$32,022
981 - Cases reporting procedures describing LITT	1	4.0	$7,348
982 - All cases	13,853	6.2	$18,176
982 - Cases reporting procedures describing LITT	5	2.2	$7,812
983- All cases	2,652	3.0	$12,163
Total	6	2.5	$7,734

In the proposed rule, we stated that for our analysis of claims from the September 2020 update of the FY 2020 MedPAR file, we identified one case reporting procedure code D0Y6KZZ (Laser interstitial thermal therapy of spinal cord) with an average length of stay of 6 days and average costs of $5,130, and two cases reporting procedure code DVY0KZZ (Laser interstitial thermal therapy of prostate) with an average length of stay of 8.5 days and average costs of $20,329 in MS–DRGs 981, 982, or 983. Although our claims analysis identified a limited number of cases reporting procedures describing LITT, we stated that our clinical advisors believe that these procedures would be more appropriately designated as Non-extensive procedures because they are more consistent with other procedures on the Non-extensive procedure code list.

Therefore, we proposed to reassign the listed procedure codes describing LITT of various body parts from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

Comment: Commenters agreed with our proposal to reassign the listed procedure codes describing LITT of various body parts from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989.

Response: We thank the commenters for their support.

After consideration of the public comments received, we are finalizing our proposal to reassign the listed procedure codes describing LITT of various body parts from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989, without modification, for FY 2022.

As also discussed in section II.D.4.b. of the preamble of the proposed rule and this final rule, we identified five procedure codes describing repair of the esophagus that are currently designated as extensive O.R. procedures. The procedure codes are 0DQ50ZZ (Repair esophagus, open approach), 0DQ53ZZ (Repair esophagus, percutaneous approach), 0DQ54ZZ (Repair esophagus, percutaneous endoscopic approach), 0DQ57ZZ (Repair esophagus, via natural or artificial opening), and 0DQ58ZZ (Repair esophagus, via natural or artificial opening endoscopic). Whenever one of these five procedure codes is reported on a claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it currently results in assignment to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Our clinical advisors stated that three of these five procedures warrant redesignation from the extensive procedure list and MS–DRGs 981, 982, and 983 to the non-extensive procedure list and to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Specifically, our clinical advisors stated the procedures identified by procedure codes 0DQ53ZZ, 0DQ57ZZ, and 0DQ58ZZ do not involve the same utilization of resources with respect to the performance of the procedure in comparison to the procedures identified by procedure codes 0DQ50ZZ and 0DQ540ZZ. In our analysis of claims from the March 2020 update of the FY 2019 MedPAR file, we identified three cases reporting procedure code 0DQ58ZZ in MS–DRGs 981, 982, and 983 with an average length of stay of 14 days and average costs of $34,894. In our analysis of claims from the September 2020 update of the FY 2020 MedPAR file, we identified two cases reporting procedure code 0DQ58ZZ in MS–DRGs 981, 982, or 983 with an average length of stay of 8 days and average costs of $12,037. We stated that our clinical advisors believe that these procedures would be more appropriately designated as Non-extensive procedures because they are more consistent with other procedures on the Non-extensive procedure code list. Therefore, we proposed to reassign these three procedure codes (0DQ53ZZ, 0DQ57ZZ, and 0DQ58ZZ) from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

Comment: Commenters supported our proposal to reassign procedure codes 0DQ53ZZ, 0DQ57ZZ, and 0DQ58ZZ from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to reassign the procedure codes describing repair of the esophagus via percutaneous approach, natural or artificial opening approach, and natural or artificial opening endoscopic approach, from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989, without modification, for FY 2022.

As discussed in section II.D.11.c.24. of the preamble of the proposed rule, we identified procedure code 0T9D0ZZ (Drainage of urethra, open approach) during our review of procedure code 0U9L0ZZ (Drainage of vestibular gland, open approach), which is currently designated as a non-O.R. procedure. We noted that the procedure described by procedure code 0T9D0ZZ represents the male equivalent of the female procedure described by procedure code 0U9L0ZZ. Procedure code 0T9D0ZZ is currently designated as an extensive O.R. procedure and is reported to describe procedures performed on the Cowper's (bulbourethral) gland in males. Whenever this procedure code is reported on a claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it currently results in assignment to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively).

In the proposed rule we noted that our clinical advisors stated that this procedure warrants redesignation from the extensive procedure list and MS–DRGs 981, 982, and 983 to the non-extensive procedure list and to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Specifically, our clinical advisors stated that the procedure described by procedure code 0T9D0ZZ continues to warrant an O.R. designation because it is performed on deeper structures and requires a higher level of technical skill and it is a more complex procedure when compared to the non-O.R. procedure described by procedure code 0U9L0ZZ, however, abscess formation in the Cowper's (bulbourethral) glands is uncommon and can often be treated with ultrasound guided percutaneous aspiration. The need for open surgical management is rare and includes chronic infection unresponsive to non-operative management and complicated acute infection such as perineal fistula formation. Open surgical management would require use of the operating room for both appropriate anesthesia and for the resources required to perform the more invasive perineal surgical dissection. Therefore, we stated that our clinical advisors believe a non-extensive O.R. designation is suitable for this procedure.

We noted in the proposed rule that we analyzed claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting procedure code 0T9D0ZZ in MS–DRGs 981, 982, and 983. We found one case in MS–DRG 981 with an average length of stay of 8.0 days and average costs of $23,566 in the March 2020 update of the FY 2019 MedPAR file, and no cases in the September 2020 update of the FY 2020 MedPAR file. Although our claims analysis identified only one case reporting procedure code 0T9D0ZZ, we stated in the proposed rule that our clinical advisors believe that these procedures would be more appropriately designated as Non-extensive procedures because they are more consistent with other procedures on the Non-extensive procedure code list.

Therefore, we proposed to reassign procedure code 0T9D0ZZ from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

Comment: Commenters supported our proposal to reassign procedure code 0T9D0ZZ from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989.

Response: We thank the commenters for their support.

After consideration of the public comments received, we are finalizing our proposal to reassign procedure code 0T9D0ZZ from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989, without modification, for FY 2022.

11. Operating Room (O.R.) and Non-O.R. Issues

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.).

Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.D.13 of the preamble of this final rule, we are

making Table 6B.—New Procedure Codes—FY 2022 available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We also refer readers to the ICD–10 MS–DRG Version 38.1 Definitions Manual at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multi year project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule that as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. type of designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of specific surgical approaches to evaluate whether to subdivide specific MS–DRGs based on a specific surgical approach. We plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), we provided a summary of the comments we had received in response to our request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration.

We stated in the proposed rule that in consideration of the PHE, we believe it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review. Additional time is also necessary as we continue to develop our process and methodology. Therefore, stated that we will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

Comment: Several commenters agreed it is appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for the comprehensive procedure code review.

Response: In the FY 2022 IPPS/LTCH PPS proposed rule and this final rule, we are addressing requests that we received regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures, or changing the designation from O.R. procedure to non-O.R. procedure. In this section of the rule we discuss the process that was utilized for evaluating the requests that were received for FY 2022 consideration. For each procedure, our clinical advisors considered—

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a nonextensive procedure; and
- To which MS–DRGs the procedure should be assigned.

We note that many MS–DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis associated with a particular MS–DRG would, by default, be grouped to that MS–DRG. Therefore, we do not list these MS–DRGs in our discussion in this section of this rule. Instead, we only discuss MS–DRGs that require explicitly adding the relevant procedure codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended. In cases where we proposed to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also proposed one or more MS–DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRG 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS–DRGs 981 through 989 in order for this to occur. Therefore, if requestors included some or all of MS–DRGs 981 through 989 in their request or included MS–DRGs that require the presence of any O.R. procedure, we did not specifically address that aspect in summarizing their request or our response to the request in this section of this rule.

For procedures that would not typically require the resources of an operating room, our clinical advisors determined if the procedure should affect the MS–DRG assignment.

As indicated in the proposed rule, we received several requests to change the designation of specific ICD–10–PCS procedure codes from non-O.R. procedures to O.R. procedures, or to change the designation from O.R. procedures to non-O.R. procedures. In this section of this rule, as we did in the proposed rule, we detail and respond to some of those requests and, further, summarize and respond to the public comments we received in response to our proposals, if applicable. With regard to the remaining requests, as stated in the proposed rule, our clinical advisors believe it is appropriate to consider these requests as part of our comprehensive review of the procedure codes as previously discussed.

With respect to some of the comments received in response to our discussion of several requests to change the designation of specific ICD–10–PCS procedure codes from non-O.R.

procedures to O.R. procedures, we wish to clarify that when we state that a current non-O.R. procedure is frequently or generally performed in the outpatient setting, we are indicating that the resources involved in the performance of the procedure are such that, it does not specifically require an inpatient admission and is typically not the underlying reason for the admission, nor a major factor in the consumption of resources for an inpatient admission. While an inpatient provider may elect to perform a specific procedure in the operating room or a procedure room, that does not constitute automatic designation of the procedure as an O.R. procedure under the IPPS. Alternatively, a procedure that is performed at the bedside does not constitute automatic designation of the procedure as a non-O.R. procedure under the IPPS. In addition, when we state that a current non-O.R. procedure is typically performed in conjunction with another O.R. procedure, we are indicating that there is generally another O.R. procedure reported on the claim that is primarily responsible for impacting the utilization of resources for that admission.

b. O.R. Procedures to Non-O.R. Procedures

(1) Open Drainage of Subcutaneous Tissue and Fascia

One requestor identified the following ICD–10–PCS procedure code that describes the open drainage of right lower leg subcutaneous tissue and fascia, shown in the following table.

ICD-10-PCS Code	Code Description
0J9N0ZZ	Drainage of right lower leg subcutaneous tissue and fascia, open approach

In the ICD–10 MS–DRG Version 38.1 Definitions Manual, this ICD–10–PCS procedure code is currently recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor noted that this procedure consumes resources comparable to related ICD–10–PCS procedure code 0J9N00Z (Drainage of right lower leg subcutaneous tissue and fascia with drainage device, open approach) that describes the open drainage of right lower leg subcutaneous tissue and fascia with a drainage device, which is currently designated as a non-O.R. procedure. The requestor stated that these comparable procedures should be recognized similarly for purposes of MS–DRG assignment.

In the proposed rule, we noted that during our review of this issue, we identified 21 ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia, shown in the following table that are clinically similar to ICD–10–PCS code 0J9N0ZZ, and are also designated as O.R. procedures in the ICD–10 MS–DRG Version 38.1 Definitions Manual.

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ICD-10-PCS Code	Code Description
0J900ZZ	Drainage of scalp subcutaneous tissue and fascia, open approach
0J910ZZ	Drainage of face subcutaneous tissue and fascia, open approach
0J940ZZ	Drainage of right neck subcutaneous tissue and fascia, open approach
0J950ZZ	Drainage of left neck subcutaneous tissue and fascia, open approach
0J960ZZ	Drainage of chest subcutaneous tissue and fascia, open approach
0J970ZZ	Drainage of back subcutaneous tissue and fascia, open approach
0J980ZZ	Drainage of abdomen subcutaneous tissue and fascia, open approach
0J990ZZ	Drainage of buttock subcutaneous tissue and fascia, open approach
0J9B0ZZ	Drainage of perineum subcutaneous tissue and fascia, open approach
0J9C0ZZ	Drainage of pelvic region subcutaneous tissue and fascia, open approach
0J9D0ZZ	Drainage of right upper arm subcutaneous tissue and fascia, open approach
0J9F0ZZ	Drainage of left upper arm subcutaneous tissue and fascia, open approach
0J9G0ZZ	Drainage of right lower arm subcutaneous tissue and fascia, open approach
0J9H0ZZ	Drainage of left lower arm subcutaneous tissue and fascia, open approach
0J9J0ZZ	Drainage of right hand subcutaneous tissue and fascia, open approach
0J9K0ZZ	Drainage of left hand subcutaneous tissue and fascia, open approach
0J9L0ZZ	Drainage of right upper leg subcutaneous tissue and fascia, open approach
0J9M0ZZ	Drainage of left upper leg subcutaneous tissue and fascia, open approach
0J9P0ZZ	Drainage of left lower leg subcutaneous tissue and fascia, open approach
0J9Q0ZZ	Drainage of right foot subcutaneous tissue and fascia, open approach
0J9R0ZZ	Drainage of left foot subcutaneous tissue and fascia, open approach

We stated we reviewed these procedures and that our clinical advisors agreed that procedures that describe the open drainage of subcutaneous tissue and fascia consume resources comparable to the related ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia with a drainage device that are currently designated as non-O.R. procedures. We stated that these procedures do not typically require the resources of an operating room, and are not surgical in nature. Therefore, we proposed to remove the 22 codes listed in the following table from the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. We stated in the proposed rule that, under this proposal, these procedures would no longer impact MS–DRG assignment.

ICD-10-PCS Code	Code Description
0J900ZZ	Drainage of scalp subcutaneous tissue and fascia, open approach
0J910ZZ	Drainage of face subcutaneous tissue and fascia, open approach
0J940ZZ	Drainage of right neck subcutaneous tissue and fascia, open approach
0J950ZZ	Drainage of left neck subcutaneous tissue and fascia, open approach
0J960ZZ	Drainage of chest subcutaneous tissue and fascia, open approach
0J970ZZ	Drainage of back subcutaneous tissue and fascia, open approach
0J980ZZ	Drainage of abdomen subcutaneous tissue and fascia, open approach
0J990ZZ	Drainage of buttock subcutaneous tissue and fascia, open approach
0J9B0ZZ	Drainage of perineum subcutaneous tissue and fascia, open approach
0J9C0ZZ	Drainage of pelvic region subcutaneous tissue and fascia, open approach
0J9D0ZZ	Drainage of right upper arm subcutaneous tissue and fascia, open approach
0J9F0ZZ	Drainage of left upper arm subcutaneous tissue and fascia, open approach
0J9G0ZZ	Drainage of right lower arm subcutaneous tissue and fascia, open approach
0J9H0ZZ	Drainage of left lower arm subcutaneous tissue and fascia, open approach
0J9J0ZZ	Drainage of right hand subcutaneous tissue and fascia, open approach
0J9K0ZZ	Drainage of left hand subcutaneous tissue and fascia, open approach
0J9L0ZZ	Drainage of right upper leg subcutaneous tissue and fascia, open approach
0J9M0ZZ	Drainage of left upper leg subcutaneous tissue and fascia, open approach
0J9N0ZZ	Drainage of right lower leg subcutaneous tissue and fascia, open approach
0J9P0ZZ	Drainage of left lower leg subcutaneous tissue and fascia, open approach
0J9Q0ZZ	Drainage of right foot subcutaneous tissue and fascia, open approach
0J9R0ZZ	Drainage of left foot subcutaneous tissue and fascia, open approach

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Comment: Commenters supported CMS' proposal to change the designation of the 22 procedure codes describing open drainage of subcutaneous tissue and fascia from O.R. procedures to non-O.R. procedures.

Response: We appreciate the commenters for their support.

Comment: Other commenters opposed CMS' proposal. Commenters stated that these procedures are indeed performed in the operating room under general anesthesia, are surgical in nature, and significantly increase costs. A commenter also stated that ICD–10–PCS codes describing open drainage ''with drainage device'' are rarely (if ever) assigned because when drains are placed at the conclusion of open drainage procedures, drains are considered integral to the performance of a procedure. Some commenters acknowledged there may be certain circumstances in which these procedures do not require an operating room but note they are not consistently conducive to being performed at bedside, especially when the patient is not able to tolerate the procedure, or when performed in for community hospitals that do not have hybrid O.R.s or special procedure rooms. A commenter stated that a review of the cases at their facility shows that approximately 80% of the procedures describing open drainage of subcutaneous tissue and fascia are performed in an O.R. setting requiring anesthesia, with a much lesser percentage performed at the bedside.

Another commenter noted in the FY 2018 IPPS proposed rule, these same 22 ICD–10–PCS codes were identified and a commenter opposed the proposal to redesignate these codes at that time. In response to the issues raised by this commenter, CMS agreed in the FY 2018 IPPS final rule to maintain the designation of the 22 procedure codes. This commenter stated the rationale to maintain these 22 codes as O.R. procedures has not changed and that there is no safe way to effectively drain an infection involving the subfascial plane without the resources of an O.R.

Response: Our clinical advisors reviewed the commenters' concerns and state that treatment practices have continued to shift since FY 2018 rulemaking. Procedures describing the open drainage of subcutaneous tissue and fascia can now be safely performed in the outpatient setting and when performed during a hospitalization, it is typically in conjunction with another O.R. procedure. In cases where procedures describing open drainage of subcutaneous tissue and fascia are the only procedures performed in an admission, the admission is quite likely due to need for IV antibiotics as opposed to the need for operating room resources in an inpatient setting. Our clinical advisors continue to state that these procedures consume resources comparable to the related ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia with a drainage device that are currently designated as non-O.R. procedures. In response to the comment that ICD–10–PCS codes describing open drainage ''with drainage device'' are rarely (if ever) assigned, while we agree there are limited scenarios in which the qualifier ''with drainage device'' is applicable, we note coding is dependent on the documentation in the medical record.

In response to the comments that differentiate when these procedures are performed at bedside versus in hybrid O.R.s versus in special procedure rooms, we note that the designation of procedure as a non-O.R. procedure is

not determined solely by the location in the facility in which the procedure was performed. While the site in which the procedure is performed and the procedural approach are important considerations in the designation of a procedure, other clinical factors such as procedure complexity, resource utilization, and need for anesthesia administration are also relevant to whether a procedure would typically require the resources of an operating room. In that regard, our clinical advisors state procedure codes that describe the open drainage of subcutaneous tissue and fascia do not reflect the technical complexity or resource intensity in comparison to other procedures that are designated as O.R. procedures. As noted by the commenters, while there are circumstances where performing open drainage in the operating room under sedation or general anesthesia may be necessary, open drainage procedures can be performed at the bedside or settings other than an operating room under general anesthesia.

We also note we have identified that the designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as O.R. procedures is a result of a replication error in transitioning to ICD–10. This replication error led to ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia being listed as comparable translations for ICD–9–CM code 83.09 (Other incision of soft tissue), which was designated as a non-extensive O.R. procedure under the ICD–9–CM MS–DRGs Version 32. Conversely, this replication error led ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia with a drainage device being listed as comparable translations for ICD–9–CM code 86.04 (Other incision with drainage of skin and subcutaneous tissue) which was designated as a non-O.R. procedure under the ICD–9–CM MS–DRGs Version 32. Designating the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as non-O.R. procedures will result in a more accurate replication of the comparable procedure, under the ICD–9–CM MS–DRGs Version 32 which was 86.04, not 83.09 and is more aligned with current shifts in treatment practices.

After consideration of the public comments we received, for the reasons stated, we are finalizing our proposal, without modification, to change the designation of the 22 procedure codes listed in the preceding table from O.R. procedures to non-O.R. procedures, effective October 1, 2021.

c. Non-O.R. Procedures to O.R. Procedures

(1) Percutaneous Introduction of Substance Into Cranial Cavity and Brain

One requestor identified ICD–10–PCS procedure code XW0Q316 (Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor recommended that this procedure be designated as an O.R. procedure because the procedure requires traversing the skull in order to place a substance within the cranial cavity or brain. The requestor noted that CMS disagreed with designating this procedure as an O.R. procedure last year in the absence of claims data; however, the requestor stated that because the skull must be opened by drilling or cutting a burr hole through the skull, this procedure warrants O.R. status similar to other transcranial procedures performed with an open or percutaneous approach that are classified as O.R. procedures.

We noted in the proposed rule that in the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure code XW0Q316 is currently designated as a non-O.R. procedure for purposes of MS–DRG assignment. We agreed with the requestor that procedure code XW0Q316 describes a procedure that involves the creation of a burr hole in the skull. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58579 through 58580), we stated that, consistent with our annual process of assigning new procedure codes to MDCs and MS–DRGs, and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignment. The predecessor code for procedure code XW0Q316 is procedure code 3E0Q3GC (Introduction of other therapeutic substance into cranial cavity and brain, percutaneous approach) which is designated as a non-O.R. procedure. In the absence of claims data, our clinical advisors also considered the indication for the specific procedure being described by the new procedure code, the treatment difficulty, and the resources utilized.

We stated in the proposed rule that upon further review and consideration, our clinical advisors agreed that procedure code XW0Q316 describing a procedure that is performed by creating a burr hole in the skull warrants designation as an O.R. procedure consistent with other percutaneous procedures performed on the cranial cavity and brain body parts. Therefore, we proposed to add this procedure code to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure, assigned to MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively).

Comment: Commenters agreed with our proposal to designate procedure code XW0Q316 as an O.R. procedure.

Response: After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure code XW0Q316 from a non-O.R. procedure to an O.R. procedure, effective October 1, 2021.

(2) Open Drainage of Maxilla and Mandible

One requestor identified three ICD–10–PCS procedure codes that describe the open drainage of maxilla or mandible that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The three procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0N9R0ZZ	Drainage of maxilla, open approach
0N9T0ZZ	Drainage of right mandible, open approach
0N9V0ZZ	Drainage of left mandible, open approach

The requestor stated that procedures that describe the open drainage of the maxilla or mandible should be designated as O.R. procedures because these procedures, indicated for diagnoses such as subperiosteal abscesses, are performed in the operating room under general anesthesia and involve making open incisions through muscle and stripping away the periosteum. The requestor identified procedure codes 0W950ZZ (Drainage of lower jaw, open approach) and 0W940ZZ (Drainage of upper jaw, open approach) that are currently designated as O.R. procedures. The requestor noted that ICD–10–PCS guidelines instruct that the procedure codes in Anatomical Regions, General, can be used when the procedure is performed on an anatomical region rather than a specific body part, or on the rare occasion when no information is available to support assignment of a code to a specific body part. The requestor stated that because bone is a specific body part in ICD–10–PCS, procedure codes should be assigned for subperiosteal drainage of mandible and maxilla bones from table 0N9, Drainage of Head and Facial Bones, instead of codes from table 0W9, Drainage of Anatomical Regions, General, when these procedures are performed. Therefore, the requestor stated that procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ should also be recognized as O.R. procedures for purposes of MS–DRG assignment.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. In the proposed rule, we stated that our clinical advisors reviewed this issue and disagreed that the procedures describing the open drainage of the maxilla or mandible are typically performed in the operating room under general anesthesia. Our clinical advisors stated that these procedures can be done in an oral surgeon's office or an outpatient setting and are rarely performed in the inpatient setting. Our clinical advisors also stated a correlation cannot be made between procedures performed in general anatomic regions and procedures performed in specific body parts because these procedures coded with the general anatomic regions body part represent a broader range of procedures that cannot be coded to a specific body part. Therefore, we proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ.

Comment: A commenter supported CMS' proposal to maintain the current non-O.R. designation for procedure codes describing open drainage of maxilla or mandible.

Response: We appreciate the commenters' support.

Comment: Another commenter opposed CMS' proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ and stated that the treatment of jaw infections requires open drainage of jaw bones performed in the operating room under anesthesia in conjunction with intravenous antibiotics to prevent sepsis. This commenter stated that procedures that are typically performed in the outpatient surgical setting should be designated as O.R. procedures and that the frequency in which procedures are performed in the inpatient setting should not determine the designation. The commenter asserted that when these procedures are necessitated during inpatient stays, providers should be compensated for operating room resources because the payment of infrequent surgeries as non-O.R. procedures results in significant uncompensated surgical resources for facilities.

Response: Our clinical advisors reviewed the commenters' concerns and continue to support maintaining the current non-O.R. designation for procedure codes describing open drainage of maxilla or mandible and disagree that the procedures describing the open drainage of the maxilla or mandible typically require the resources of an operating room. Our clinical advisors state that if admission is required for the treatment of a jaw infection as the commenter suggested, the admission is quite likely due to need for IV antibiotics as opposed to the need for operating room resources in an inpatient setting.

With regard to the comments about the implications for reimbursement, we note that the goals of changing the designation of procedures from non-O.R. to O.R., or vice versa, are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system. Therefore, decisions to change an O.R. designation are based on whether such a change would accomplish those goals and not whether the change in designation would impact the payment in a particular direction.

After consideration of the public comments we received, for the reasons stated, we are finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ, without modification, for FY 2022.

(3) Thoracoscopic Extirpation of Pleural Cavities

One requestor identified ICD–10–PCS procedure codes 0WC94ZZ (Extirpation of matter from right pleural cavity, percutaneous endoscopic approach) and 0WCB4ZZ (Extirpation of matter from left pleural cavity, percutaneous endoscopic approach) that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor stated that these procedures should be designated as O.R. procedures because they are thoracoscopic procedures that are always performed in the operating room under general anesthesia. The requestor stated procedure codes 0W994ZZ (Drainage of right pleural cavity, percutaneous endoscopic approach) and 0W9B4ZZ (Drainage of left pleural cavity, percutaneous endoscopic approach) are currently designated as O.R. procedures, therefore procedure codes 0WC94ZZ and 0WCB4ZZ should also be recognized as O.R. procedures for purposes of MS–DRG assignment because they utilize the same resources.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0WC94ZZ and 0WCB4ZZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. We stated in the proposed rule that our clinical advisors reviewed this issue and

disagreed that procedure codes describing the thoracoscopic drainage of the pleural cavities should necessarily have the same designation as procedure codes describing the thoracoscopic extirpation of matter from the pleural cavities. We noted that our review of the designation of ICD–10–PCS codes as an O.R. procedure or a non-O.R. procedure considers the resources used as well as whether that procedure should affect the MS–DRG assignment, and if so, in what way. Our clinical advisors stated that thoracoscopic drainage of the pleural cavities is performed for distinct indications in clinically different scenarios. Our clinical advisors further stated that drainage is the process of taking out, or letting out, fluids and/or gases from a body part and is typically performed in the pleural cavity for indications such as congestive heart failure, infection, hemothorax and empyema. In contrast, the procedures describing the thoracoscopic extirpation of the pleural cavities are performed for a wider range of indications because the solid matter removed may be an abnormal byproduct of a biological function or a foreign body. Our clinical advisors noted that the thoracoscopic extirpation of the pleural cavities is generally performed with other procedures such as heart transplant, lung transplant mechanical ventilation, and other major chest procedures and would not be the main reason for inpatient hospitalization or be considered the principal driver of resource expenditure.

Therefore, we proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0WC94ZZ and 0WCB4ZZ.

Comment: A commenter supported CMS' proposal to maintain the current non-O.R. designation for procedure codes describing the thoracoscopic extirpation of matter from the pleural cavities.

Response: We appreciate the commenters' support.

Comment: Another commenter opposed CMS' proposal to maintain the non-O.R. designation of ICD–10–PCS procedure codes 0WC94ZZ and 0WCB4ZZ. The commenter stated that procedure codes describing the thoracoscopic extirpation of matter from the pleural cavities can indeed be primary surgical procedures in procedures such as when the thoracoscopic evacuation of a traumatic hemothorax is performed during hospitalization, and stated that all thoracoscopic lung procedures should be designated as O.R. procedures because they are performed in the operating room and require general anesthesia with one lung ventilation. This commenter also stated that ICD–10–PCS codes for thoracoscopic drainage of pleural cavities have been appropriately designated as O.R. procedures, and the only difference between root operations ''Drainage'' and ''Extirpation'' is strictly the consistency of the substance removed.

Response: Our clinical advisors reviewed the commenters' concerns and continue to support maintaining the current non-O.R. designation for procedure codes of ICD–10–PCS procedure codes 0WC94ZZ and 0WCB4ZZ because the resources involved in furnishing these procedures does not warrant designation as O.R. procedures. Our clinical advisors continue to state the thoracoscopic extirpation of the pleural cavities is generally performed with other procedures such as heart transplant, lung transplant mechanical ventilation, and other major chest procedures and would not be the main reason for inpatient hospitalization or be considered the principal driver of resource expenditure. Our clinical advisors also do not agree that unilaterally all thoracoscopic lung procedures should be designated as O.R. procedures.

Our clinical advisors reiterate that thoracoscopic drainage of the pleural cavities and thoracoscopic extirpation of the pleural cavities are performed for distinct indications in clinically different scenarios and disagree with the suggestion that the only difference between the PCS root operations ''Drainage'' and ''Extirpation'' is the consistency of the substance removed. Rather, drainage procedures take out, or let out, fluids and/or gases from a body part and are typically performed in the pleural cavity for indications such as congestive heart failure, infection, hemothorax and empyema. Extirpation procedures are not limited to removing blood clots. In contrast, the procedures describing the thoracoscopic extirpation of the pleural cavities are performed for a wider range of indications because the solid matter removed may be an abnormal byproduct of a biological function or a foreign body.

In response to the commenter that stated highlighted the thoracoscopic evacuation of a traumatic hemothorax as an example of how these procedures can indeed be primary surgical procedures, we note hemothorax is defined as a collection of blood in the pleural cavity. The thoracoscopic evacuation of a hemothorax would meet the ICD–10–PCS definition of a ''Drainage'' procedure. The procedure codes describing the drainage of the pleural cavity were not the subject of this request.

After consideration of the public comments we received, for the reasons stated, we are finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0WC94ZZ and 0WCB4ZZ, without modification, for FY 2022.

(4) Open Pleural Biopsy

One requestor identified ICD–10–PCS procedure codes 0BBN0ZX (Excision of right pleura, open approach, diagnostic) and 0BBP0ZX (Excision of left pleura, open approach, diagnostic), that describe an open pleural biopsy that the requestor stated are performed in the operating room with general anesthesia. The requestor also stated that procedure codes 0BBN0ZZ (Excision of right pleura, open approach) and 0BBP0ZZ (Excision of left pleura, open approach) describing open pleural biopsy for non-diagnostic purposes are justifiably designated as O.R. procedures. According to the requestor, these procedure codes describing an open pleural biopsy should be designated as O.R. procedures regardless of whether they are performed for diagnostic or therapeutic purposes.

In the proposed rule we noted that under the ICD–10–PCS procedure classification, biopsy procedures are identified by the 7th digit qualifier value ''diagnostic'' in the code description. In response to the requestor's suggestion that procedures performed for a pleural biopsy by an open approach, regardless of whether it is a diagnostic or therapeutic procedure, should be designated as an O.R. procedure, we examined procedure codes 0BBN0ZX, 0BBN0ZZ, 0BBP0ZX, and 0BBP0ZZ.

We also noted that in the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0BBN0ZZ and 0BBP0ZZ are currently designated as O.R. procedures, however, procedure codes 0BBN0ZX and 0BBP0ZX are not recognized as O.R. procedures for purposes of MS–DRG assignment. We agreed with the requestor that procedure codes 0BBN0ZX and 0BBP0ZX would typically require the resources of an operating room. We stated that our clinical advisors also agreed that procedure codes 0BBN0ZX and 0BBP0ZX would typically require the resources of an operating room. Therefore, we proposed to add these 2 procedure codes to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 166, 167, and 168

(Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 04 (Diseases and Disorders of the Respiratory System).

Comment: Commenters supported our proposal to designate procedure codes 0BBN0ZX and 0BBP0ZX as O.R. procedures.

Response: After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure codes 0BBN0ZX and 0BBP0ZX from non-O.R. procedures to O.R. procedures, without modification, effective October 1, 2021.

(5) Percutaneous Revision of Intraluminal Devices

One requestor identified five ICD–10–PCS procedure codes that describe the percutaneous revision of intraluminal vascular devices that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The five procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
02WY3DZ	Revision of intraluminal device in the great vessel, percutaneous approach
03WY3DZ	Revision of intraluminal device in upper artery, percutaneous approach
04WY3DZ	Revision of intraluminal device in lower artery, percutaneous approach
05WY3DZ	Revision of intraluminal device in upper vein, percutaneous approach
06WY3DZ	Revision of intraluminal device in lower vein, percutaneous approach

The requestor stated that the procedure codes that describe the percutaneous revision of intraluminal vascular devices within arteries, veins, and great vessels should be designated as O.R. procedures to compensate for the resources needed to perform these procedures. The requestor also stated procedures to reattach, realign, or otherwise revise intraluminal devices percutaneously require anesthesia, specialized equipment for intravascular visualization, significant skill, and time, therefore, it is important for these codes to be designated with O.R. procedure status.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 02WY3DZ, 03WY3DZ, 04WY3DZ, 05WY3DZ, and 06WY3DZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. We stated in the proposed rule that we agreed with the requestor that these five ICD–10–PCS procedure codes typically require the resources of an operating room. Therefore, to the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, we proposed to add code 02WY3DZ as an O.R. procedure assigned to MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System). We also proposed to add codes 03WY3DZ, 04WY3DZ, 05WY3DZ, and 06WY3DZ as O.R. procedures assigned to MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System).

Comment: Commenters supported our proposal to designate ICD–10–PCS procedure codes 02WY3DZ, 03WY3DZ, 04WY3DZ, 05WY3DZ, and 06WY3DZ as O.R. procedures. A commenter noted that they agreed that these procedures do typically require the resources of an operating room.

Response: After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure code 02WY3DZ from a non-O.R. procedure to an O.R. procedure, effective October 1, 2021, without modification. We are also finalizing our proposal to change the designation of procedure codes 03WY3DZ, 04WY3DZ, 05WY3DZ, and 06WY3DZ from non-O.R. procedures to O.R. procedure, without modification, effective October 1, 2021.

(6) Occlusion of Left Atrial Appendage

One requestor identified nine ICD–10–PCS procedure codes that describe left atrial appendage closure (LAAC) procedures that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment in all instances. The nine procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
02L70CK	Occlusion of left atrial appendage with extraluminal device, open approach
02L70DK	Occlusion of left atrial appendage with intraluminal device, open approach
02L70ZK	Occlusion of left atrial appendage, open approach
02L73CK	Occlusion of left atrial appendage with extraluminal device, percutaneous approach
02L73DK	Occlusion of left atrial appendage with intraluminal device, percutaneous approach
02L73ZK	Occlusion of left atrial appendage, percutaneous approach
02L74CK	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic approach
02L74DK	Occlusion of left atrial appendage with intraluminal device, percutaneous endoscopic approach
02L74ZK	Occlusion of left atrial appendage, percutaneous endoscopic approach

The requestor stated that these procedures are currently designated as non-O.R. procedures that route to surgical MS–DRGs only when assigned in combination with a principal diagnosis within MDC 05 (Diseases and Disorders of the Circulatory System). The requestor stated these procedures should also be designated as O.R. procedures when assigned in combination with diagnoses outside of the circulatory system, such as sepsis or trauma, to compensate for the associated resource use, skill requirements, and device costs.

In the ICD–10 MS–DRG Version 38.1 Definitions Manual, the nine ICD–10–PCS procedure codes that describe left atrial appendage closure are currently recognized as non-O.R. procedures that affect the MS–DRG to which they are assigned. We refer readers to section II.D.5.d of the preamble of this final rule, where we address ICD–10–PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK that describe a LAAC procedure performed with an open approach. These codes were discussed in response to a request to reassign these codes to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively). In section II.D.5.d of this final rule we also summarize and respond to the comments regarding our proposal to maintain the assignment of these codes in MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively) in MDC 05 for the reasons discussed, and discuss our finalization of that proposal.

We stated in the proposed rule that our clinical advisors reviewed this related issue and believed the current designation of LAAC procedures as non-O.R. procedures that affect the assignment for MS–DRGs 273 and 274 is clinically appropriate to account for the subset of patients undergoing left atrial appendage closure specifically. LAAC is indicated and approved as a treatment option for patients diagnosed with atrial fibrillation, a heart rhythm disorder that can lead to cardiovascular blood clot formation, who are also at increased risk for stroke. LAAC procedures block off the left atrial appendage to prevent emboli that may form in the left atrial appendage from exiting and traveling to other sites in the vascular system, thereby preventing the occurrence of ischemic stroke and systemic thromboembolism. We noted the ICD–10–CM diagnosis codes used to report atrial fibrillation are currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System). We stated our clinical advisors believed that circumstances in which a patient is admitted for a principal diagnosis outside of MDC 05 and a left atrial appendage closure is performed as the only surgical procedure in the same admission are infrequent, and if they do occur, the LAAC procedure would not be a significant contributing factor in the increased intensity of resources needed for facilities to manage these complex cases. Our clinical advisors further stated LAAC procedures generally do not require the resources of an operating room. LAAC procedures are most often performed percutaneously in settings such as cardiac catheterization laboratories and take approximately one hour. We stated when performed with an open approach or percutaneous endoscopic approach, these procedures share similar factors such as complexity, and resource utilization with all other LAAC procedures. Therefore, we proposed to maintain the current designation of ICD–10–PCS procedure codes 02L70CK, 02L70DK, 02L70ZK, 02L73CK, 02L73DK, 02L73ZK, 02L74CK, 02L74DK, and 02L74ZK as non-O.R. procedures affecting the MS–DRGs to which they are assigned.

Comment: Commenters supported maintaining the current designation of procedure codes describing left atrial appendage closure as non-O.R. procedures affecting the MS–DRGs to which they are assigned. Another commenter stated although they believe it would be reasonable for these PCS codes to be designated as O.R. procedures in the event they are necessitated during a hospitalization with a principal diagnosis outside of MDC 05, their own data analysis showed when performed, cases reporting LAAC procedures are being assigned to MS–DRGs 273 and 274 or into higher-weighted cardiac MS–DRGs corresponding with other cardiac procedures performed during the same stay.

Response: After consideration of the public comments we received, we are finalizing our proposal to maintain the current designation of ICD–10–PCS procedure codes 02L70CK, 02L70DK, 02L70ZK, 02L73CK, 02L73DK, 02L73ZK, 02L74CK, 02L74DK, and 02L74ZK as non-O.R. procedures affecting the MS–DRGs to which they are assigned, without modification, for FY 2022.

(7) Arthroscopic Drainage of Joints

One requestor identified six ICD–10–PCS procedure codes that describe the percutaneous endoscopic drainage of joints that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The six procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0S9C4ZZ	Drainage of right knee joint, percutaneous endoscopic approach
0S9D4ZZ	Drainage of left knee joint, percutaneous endoscopic approach
0S994ZZ	Drainage of right hip joint, percutaneous endoscopic approach
0S9B4ZZ	Drainage of left hip joint, percutaneous endoscopic approach
0R9J4ZZ	Drainage of right shoulder joint, percutaneous endoscopic approach
0R9K4ZZ	Drainage of left shoulder joint, percutaneous endoscopic approach

The requestor stated that these procedures should be designated as O.R. procedures because procedures describing the arthroscopic drainage of major joints such as knee, hip, and shoulder are performed in the operating room under general anesthesia. The requestor stated these procedures are indicated for conditions such as symptomatic septic/pyogenic arthritis, which can require inpatient admission for intravenous antibiotics and arthroscopic drainage to resolve infection. Therefore, the requestor stated it is reasonable for these arthroscopic procedures to be designated as O.R. procedures to compensate for operating room resources.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0S9C4ZZ, 0S9D4ZZ, 0S994ZZ, 0S9B4ZZ, 0R9J4ZZ, and 0R9K4ZZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. In the proposed rule, we stated our clinical advisors reviewed this issue and disagreed that procedures describing the percutaneous endoscopic drainage of major joints such as knee, hip, and shoulder are typically performed in the operating room under general anesthesia. With development of better instrumentation and surgical techniques, many patients now have arthroscopic procedures performed in an outpatient setting and return home several hours after the procedure. Our clinical advisors also stated the percutaneous endoscopic drainage of joints can be performed using local or regional anesthesia, and general anesthesia is not always required. We stated that in cases where the patient is admitted for diagnoses such as septic/pyogenic arthritis, as identified by the requestor, the requirement for intravenous antibiotics would be the main reason for admission because the percutaneous endoscopic drainage procedure could be done as an outpatient. Therefore, we proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0S9C4ZZ, 0S9D4ZZ, 0S994ZZ, 0S9B4ZZ, 0R9J4ZZ, and 0R9K4ZZ.

Comment: A commenter supported CMS' proposal to maintain the non-O.R. designation of procedure codes describing percutaneous endoscopic drainage of shoulder, knee, and hip joints.

Response: We appreciate the commenters' support.

Comment: A commenter opposed CMS' proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0S9C4ZZ, 0S9D4ZZ, 0S994ZZ, 0S9B4ZZ, 0R9J4ZZ, and 0R9K4ZZ. This commenter stated that an O.R. designation should not be determined based on whether or not a surgery is most often performed as an outpatient or based on the type anesthesia required during the surgery. This commenter also noted that some patients who undergo outpatient surgery require inpatient admission instead of release home. The commenter stated that retention of non-O.R. procedure status for surgeries most often performed as outpatient results in providers not being reimbursed for surgical resources when patients require conversion to inpatient, while those discharged from outpatient surgery are paid a surgical APC. The commenter also included a portion of an operative report from its facility to demonstrate that an arthroscopic drainage procedure was performed under general anesthesia at their facility.

Response: Our clinical advisors reviewed the commenters' concerns and continue to support maintaining the current non-O.R. designation for ICD–10–PCS procedure codes 0S9C4ZZ, 0S9D4ZZ, 0S994ZZ, 0S9B4ZZ, 0R9J4ZZ, and 0R9K4ZZ. In reviewing the operative report included in the comment, our clinical advisors note that using a single isolated case, with only an operative report provided and without other diagnostic information on the patient, does not provide a clear picture of the circumstances of that admission, nor does it inform whether the procedure requires the resources of an operating room more broadly. For any procedure, there may be instances where performing this procedure is best done in the setting of an operative room using general anesthesia. However, when looking more broadly at the procedure being described by the ICD–10–PCS codes 0S9C4ZZ, 0S9D4ZZ, 0S994ZZ, 0S9B4ZZ, 0R9J4ZZ, and 0R9K4ZZ, our clinical advisors state in most instances, the percutaneous endoscopic drainage of joints does not require the resources of an operative room.

With regard to the comments about the implications for reimbursement when cases are converted from outpatient to inpatient, we note that the goals of changing the designation of procedures from non-O.R. to O.R., or vice versa, are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system.

Therefore, after consideration of the public comments we received, for the reasons stated, we are finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0S9C4ZZ, 0S9D4ZZ, 0S994ZZ, 0S9B4ZZ, 0R9J4ZZ, and 0R9K4ZZ, without modification, for FY 2022.

(8) Arthroscopic Irrigation of Joints

One requestor identified ICD–10–PCS procedure codes 3E1U48X (Irrigation of joints using irrigating substance, percutaneous endoscopic approach, diagnostic) and 3E1U48Z (Irrigation of joints using irrigating substance,

percutaneous endoscopic approach) that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor stated that these procedures should be designated as O.R. procedures because the arthroscopic irrigation of joints such as knee, hip, and shoulder is performed in the operating room under general anesthesia. The requestor states procedure codes 3E1U48X and 3E1U48Z are used to describe surgical joint irrigations in the absence of more definitive procedures, therefore procedure codes 3E1U48X and 3E1U48Z should be recognized as O.R. procedures for purposes of MS–DRG assignment.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 3E1U48X and 3E1U48Z are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. In the proposed rule, we stated that our clinical advisors reviewed this issue and disagreed that procedure codes describing the arthroscopic irrigation of joints should be designated as O.R. procedures. Our clinical advisors noted the arthroscopic irrigation of joints is rarely performed independently as a standalone procedure in the inpatient setting to be considered the principal driver of resource expenditure in those admissions. Instead, the arthroscopic irrigation of joints is generally performed with other definitive procedures such as debridement or synovectomy. We noted that in the operative note sent by the requestor to support the requested change in O.R. status, the arthroscopic irrigation of the joint was performed along with a surgical debridement procedure. Therefore, we proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 3E1U48X and 3E1U48Z.

Comment: A commenter supported CMS' proposal to maintain the non-O.R. designation of procedure codes describing arthroscopic irrigation of joints.

Response: We appreciate the commenters' support.

Comment: Another commenter opposed CMS' proposal to maintain the non-O.R. designation of ICD–10–PCS procedure codes 3E1U48X and 3E1U48Z. This commenter acknowledged that arthroscopic irrigations may be performed with other definitive procedures such as bone debridement and synovectomy, but stated that some are indeed performed as sole definitive operating room procedures. This commenter stated there are no other PCS codes for irrigational debridement of joints; when minor debridement is performed in conjunction with more significant primary procedures, minor debridement is considered inherent and not separately reportable.

Response: We appreciate the commenters' feedback. We are unclear from the comment why the commenter references the ICD–10–PCS guidelines related to debridement procedures, as this topic relates to the arthroscopic irrigation of joints. Our clinical advisors reviewed the commenters' concerns and continue to note the arthroscopic irrigation of joints is rarely performed independently as a standalone procedure in the inpatient setting to be considered the principal driver of resource expenditure in those admissions.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 3E1U48X and 3E1U48Z, without modification, for FY 2022.

(9) Percutaneous Reposition With Internal Fixation

One requestor identified four ICD–10–PCS procedure codes describing procedures performed on the sacroiliac and hip joints that involve percutaneous repositioning with internal fixation that the requestor stated are not recognized as O.R. procedures for purposes of MS–DRG assignment but warrant an O.R. designation. The procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0SS734Z	Reposition right sacroiliac joint with internal fixation device, percutaneous approach
0SS834Z	Reposition left sacroiliac joint with internal fixation device, percutaneous approach
0SS934Z	Reposition right hip joint with internal fixation device, percutaneous approach
0SSB34Z	Reposition left hip joint with internal fixation device, percutaneous approach

We stated in the proposed rule that our clinical advisors reviewed the procedures described by these four procedure codes and agreed that these percutaneous reposition procedures involving internal fixation in the sacroiliac and hip joint warrant an O.R. designation. They noted that these procedures are major operations that would require the resources of an operating room, involve a higher level of technical complexity and a greater utilization of hospital resources.

Therefore, we proposed to add the two procedure codes describing percutaneous reposition of the sacroiliac joint with internal fixation procedures (0SS734Z and 0SS834Z) to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively). We also proposed to add the two procedure codes describing percutaneous reposition of the hip joint with internal fixation procedures (0SS934Z and 0SSB34Z) to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS– DRG Index as O.R. procedures, assigned to MS–DRGs 480, 481, and 482 (Hip and Femur Procedures Except Major Joint with MCC, with CC, and without CC/MCC, respectively) in MDC 08 (Diseases and Disorders of the Musculoskeletal System

and Connective Tissue) and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively).

Comment: Commenters supported our proposal to designate procedure codes 0SS734Z, 0SS834Z, 0SS934Z and 0SSB34Z as O.R. procedures.

Response: After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure codes 0SS734Z, 0SS834Z, 0SS934Z and 0SSB34Z from non-O.R. procedures to O.R. procedures, without modification, effective October 1, 2021.

(10) Open Insertion and Removal of Spacer Into Shoulder Joint

One requestor identified four ICD–10–PCS procedure codes describing procedures performed on the shoulder joint that involve the insertion or removal of a spacer by an open approach that the requestor stated are not recognized as O.R. procedures for purposes of MS–DRG assignment. The procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0RHK08Z	Insertion of spacer into left shoulder joint, open approach
0RHJ08Z	Insertion of spacer into right shoulder joint, open approach
0RPK08Z	Removal of spacer from left shoulder joint, open approach
0RPJ08Z	Removal of spacer from right shoulder joint, open approach

According to the requestor, insertion and removal of joint spacers from the hips and knees are designated with an O.R. procedure status and although similar procedures performed on the shoulder joint may be performed less frequently, these procedures warrant an O.R. designation because they are performed in the operating room under general anesthesia.

In the proposed rule we stated that during our review, we noted that the following procedure codes describing procedures performed on the shoulder joint that involve the insertion or removal of a spacer by a percutaneous endoscopic approach are also not recognized as O.R. procedures for purposes of MS–DRG assignment.

ICD-10-PCS Code	Code Description
0RPJ48Z	Removal of spacer from right shoulder joint, percutaneous endoscopic approach
0RPK48Z	Removal of spacer from left shoulder joint, percutaneous endoscopic approach
0RHJ48Z	Insertion of spacer into right shoulder joint, percutaneous endoscopic approach
0RHK48Z	Insertion of spacer into left shoulder joint, percutaneous endoscopic approach

We stated that our clinical advisors reviewed the procedures described by these eight procedure codes and agreed that these procedures involving the insertion or removal of a spacer in the shoulder joint with an open or percutaneous endoscopic approach warrant an O.R. designation. They noted that the insertion of a spacer is typically performed to treat an infection at the site of a previously placed prosthesis and the removal of a spacer is typically performed once the infection is healed and the site is ready for a new prosthetic replacement or to exchange for a new spacer if the infection is not yet healed.

Therefore, we proposed to add the listed procedure codes describing the insertion or removal of spacer in the shoulder joint to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 510, 511, and 512 (Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively).

Comment: Commenters supported our proposal to designate the listed procedure codes as O.R. procedures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure codes 0RHK08Z, 0RHJ08Z, 0RPK08Z, 0RPJ08Z, 0RPJ48Z, 0RPK48Z, 0RHJ48Z, and 0RHK48Z from non-O.R. procedures to O.R. procedures, without modification, effective October 1, 2021.

(11) Open/Percutaneous Extirpation of Jaw

One requestor identified four ICD–10–PCS procedure codes that describe the extirpation of matter from the upper or lower jaw that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The four procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0WC40ZZ	Extirpation of matter from upper jaw, open approach
0WC44ZZ	Extirpation of matter from upper jaw, percutaneous endoscopic approach
0WC50ZZ	Extirpation of matter from lower jaw, open approach
0WC54ZZ	Extirpation of matter from lower jaw, percutaneous endoscopic approach

The requestor stated that the procedure codes that describe the extirpation of matter from the upper or lower jaw by an open or percutaneous endoscopic approach should be designated as O.R. procedures. The requestor stated these procedures would commonly be performed under general anesthesia and require the resources of an operating room. The requestor also stated that these ICD–10–PCS codes were specifically created to describe the surgical evacuation of solid matter from deep jaw structures therefore, it is important for these codes to be designated with O.R. procedure status.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0WC40ZZ, 0WC44ZZ, 0WC50ZZ, 0WC54ZZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. We stated in the proposed rule that we agreed with the requestor that these four ICD–10–PCS procedure codes typically require the resources of an operating room. Therefore, to the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, we proposed to add codes 0WC40ZZ, 0WC44ZZ, 0WC50ZZ, 0WC54ZZ as O.R. procedures assigned to MS–DRGs 143, 144 and 145 (Other Ear, Nose, Mouth and Throat O.R. procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat).

Comment: Commenters supported our proposal to designate ICD–10–PCS procedure codes 0WC40ZZ, 0WC44ZZ, 0WC50ZZ, and 0WC54ZZ as O.R. procedures. A commenter noted that they agreed that these procedures do typically require the resources of an operating room.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure codes 0WC40ZZ, 0WC44ZZ, 0WC50ZZ, 0WC54ZZ from non-O.R. procedures to O.R. procedures, without modification, effective October 1, 2021.

(12) Open Extirpation of Subcutaneous Tissue and Fascia

One requestor identified 22 ICD–10–PCS procedure codes that describe the open extirpation of matter from the subcutaneous tissue and fascia that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The 22 procedure codes are listed in the following table.

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ICD-10-PCS Code	Code Description
0JC00ZZ	Extirpation of matter from scalp subcutaneous tissue and fascia, open approach
0JC10ZZ	Extirpation of matter from face subcutaneous tissue and fascia, open approach
0JC40ZZ	Extirpation of matter from right neck subcutaneous tissue and fascia, open approach
0JC50ZZ	Extirpation of matter from left neck subcutaneous tissue and fascia, open approach
0JC60ZZ	Extirpation of matter from chest subcutaneous tissue and fascia, open approach
0JC70ZZ	Extirpation of matter from back subcutaneous tissue and fascia, open approach
0JC80ZZ	Extirpation of matter from abdomen subcutaneous tissue and fascia, open approach
0JC90ZZ	Extirpation of matter from buttocks subcutaneous tissue and fascia, open approach
0JCB0ZZ	Extirpation of matter from perineum subcutaneous tissue and fascia, open approach
0JCC0ZZ	Extirpation of matter from pelvic region subcutaneous tissue and fascia, open approach
0JCD0ZZ	Extirpation of matter from right upper arm subcutaneous tissue and fascia, open approach
0JCF0ZZ	Extirpation of matter from left upper arm subcutaneous tissue and fascia, open approach
0JCG0ZZ	Extirpation of matter from right lower arm subcutaneous tissue and fascia, open approach
0JCH0ZZ	Extirpation of matter from left lower arm subcutaneous tissue and fascia, open approach
0JCJ0ZZ	Extirpation of matter from right hand subcutaneous tissue and fascia, open approach
0JCK0ZZ	Extirpation of matter from left hand subcutaneous tissue and fascia, open approach
0JCL0ZZ	Extirpation of matter from right upper leg subcutaneous tissue and fascia, open approach
0JCM0ZZ	Extirpation of matter from left upper leg subcutaneous tissue and fascia, open approach
0JCN0ZZ	Extirpation of matter from right lower leg subcutaneous tissue and fascia, open approach
0JCP0ZZ	Extirpation of matter from left lower leg subcutaneous tissue and fascia, open approach
0JCQ0ZZ	Extirpation of matter from right foot subcutaneous tissue and fascia, open approach
0JCR0ZZ	Extirpation of matter from left foot subcutaneous tissue and fascia, open approach

BILLING CODE 4120–01–C

The requestor stated that procedure codes that describe the open extirpation of matter from the subcutaneous tissue and fascia should be designated as O.R. procedures because these procedures are performed through open incisions with direct visualization of subcutaneous tissue and fascia in the operating room under general anesthesia. The requestor noted procedure codes that describe the open drainage of subcutaneous tissue and fascia and use comparable resources are currently designated as O.R. procedures. The requestor noted that root operation ''Drainage'' is assigned when fluid is drained; and root operation of ''Extirpation'' is assigned when any of the substance evacuated is solid. The requestor stated whether the evacuated substance is fluid, gelatinous, or solid, a procedure involving an open incision with direct visualization of subcutaneous tissue and fascia for evacuation of substances should be classified as an O.R. procedure. Therefore, the requestor stated that these procedures should also be recognized as O.R. procedures for purposes of MS–DRG assignment.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, the 22 ICD–10–PCS procedure codes listed in the table are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. We stated in the proposed rule that while we disagreed that drainage procedures are comparable to extirpation procedures, we agreed with the requestor that these 22 ICD–10–PCS procedure codes typically require the resources of an operating room. We noted that our clinical advisors stated that drainage is the process of taking out, or letting out, fluids and/or gases from a body part and is typically performed for indications such as abscess, infection, and other systemic conditions. In contrast, extirpation procedures are performed for a wider range of indications because the solid matter removed may be an abnormal byproduct of a biological function or a retained foreign body. Therefore, to the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, we proposed to add the 22 ICD–10–PCS listed previously as O.R. procedures assigned to MS–DRGs 579, 580 and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs).

Comment: Commenters supported our proposal to designate 22 ICD–10–PCS procedure codes that describe the open extirpation of matter from the subcutaneous tissue and fascia as O.R. procedures. A commenter noted that they agreed that open incision with direct visualization of subcutaneous tissue and fascia for the evacuation of a substance typically requires the resources of an operating room.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 22 procedure codes

listed in the preceding table from non-O.R. procedures to O.R. procedures, without modification, effective October 1, 2021.

(13) Open Revision and Removal of Devices From Subcutaneous Tissue and Fascia

One requestor identified six ICD–10–PCS procedure codes describing open revision and removal of neurostimulator generators, monitoring devices, and totally implantable vascular access devices (TIVADs) procedures that are not currently designated as O.R. procedures for purposes of MS–DRG assignment. The six procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0JPT0MZ	Removal of stimulator generator from trunk subcutaneous tissue and fascia, open approach
0JPT02Z	Removal of monitoring device from trunk subcutaneous tissue and fascia, open approach
0JPT0WZ	Removal of totally implantable vascular access device from trunk subcutaneous tissue and fascia, open approach
0JWT0MZ	Revision of stimulator generator from trunk subcutaneous tissue and fascia, open approach
0JWT0WZ	Revision of totally implantable vascular access device from trunk subcutaneous tissue and fascia, open approach
0JWT03Z	Revision of infusion device in trunk subcutaneous tissue and fascia, open approach

The requestor stated that although removal of these devices is often performed in outpatient surgery, device complications can require removal or revision during inpatient hospitalizations. The requestor indicated it is reasonable for these open procedures to be designated as O.R. procedures to compensate for operating room resources during such inpatient stays.

In the proposed rule we stated that our clinical advisors reviewed this request and did not agree that these procedures warrant an O.R. designation. They noted that these procedures are generally performed in the outpatient setting and when performed during a hospitalization, it is typically in conjunction with another O.R. procedure. Therefore, we proposed to maintain the current non-O.R. designation for procedure codes 0JPT0MZ, 0JPT02Z, 0JPT0WZ, 0JWT0MZ, 0JWT0WZ, and 0JWT03Z for FY 2022.

Comment: Commenters supported our proposal to maintain the non-O.R. designation for procedure codes 0JPT0MZ, 0JPT02Z, 0JPT0WZ, 0JWT0MZ, 0JWT0WZ, and 0JWT03Z.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation for procedure codes 0JPT0MZ, 0JPT02Z, 0JPT0WZ, 0JWT0MZ, 0JWT0WZ, and 0JWT03Z, effective October 1, 2021.

(14) Open Insertion of Feeding Device

One requestor identified ICD–10–PCS procedure code 0DHA0UZ (Insertion of feeding device into jejunum, open approach) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor stated the open insertion of a feeding device into the jejunum should be designated as an O.R. procedure because this procedure is performed in the operating room under general anesthesia. The requestor noted comparable procedure code 0DH60UZ (Insertion of feeding device into stomach, open approach) is currently designated as an O.R. procedure. Therefore, the requestor stated that procedure code 0DHA0UZ should also be recognized as an O.R. procedure for purposes of MS–DRG assignment.

We stated in the proposed rule that our analysis of this issue confirmed that in the ICD–10 MS–DRG Version 38.1 Definitions Manual, for purposes of MS–DRG assignment, 0DHA0UZ is recognized as a non-O.R. procedure and 0DH60UZ is currently recognized as an O.R. procedure. We stated that in reviewing this request, we also identified the following four related codes:

ICD-10-PCS Code	Code Description
0DH50UZ	Insertion of feeding device into esophagus, open approach
0DH80UZ	Insertion of feeding device into small intestine, open approach
0DH90UZ	Insertion of feeding device into duodenum, open approach
0DHB0UZ	Insertion of feeding device into ileum, open approach

In the ICD–10 MS–DRGs Version 38.1, these four ICD–10–PCS codes are currently recognized as non-O.R. procedure for purposes of MS–DRG assignment. In the proposal rule, we stated that while we agreed with the requestor that procedures describing the open insertion of a feeding device into the jejunum are comparable to procedures describing the open insertion of a feeding device into the stomach, we did not agree that these procedures should be designated as O.R. procedures. Our clinical advisors stated the procedures that describe the open insertion of a feeding device into the jejunum or the stomach should instead have the same designation as the related ICD–10–PCS procedure codes that describe the open insertion of a feeding device into the esophagus, small intestine, duodenum and ileum that are currently designated as non-O.R. procedures.

We noted with advancements in procedural techniques, feeding devices are most commonly placed using a percutaneous endoscopic approach. Our clinical advisors further stated feeding devices are usually not placed using an open surgical approach; this approach is generally only used if the patient requires another surgical procedure at the same time. When placed at the same time as another surgical procedure, our clinical advisors stated the surgical procedure, as the main determinant of resource use for those cases, should drive the MS–DRG assignment, not the procedure that describes the open insertion of a feeding device. For these reasons, our clinical advisors stated procedures that describe the open insertion of a feeding device in the gastrointestinal system should all have the same non-O.R. designation in the ICD–10 MS–DRGs Version 39 for coherence.

Therefore, we proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure code 0DHA0UZ. We also proposed to remove ICD–10–PCS procedure code 0DH60UZ from the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure. We stated in the proposed rule that, under this proposal, this procedure would no longer impact MS–DRG assignment.

Comment: A commenter supported CMS' proposal and stated they agreed that neither the procedure code describing open insertion of feeding device into stomach nor the procedure code describing open insertion of feeding device into jejunum should be designated as an O.R. procedure.

Response: We appreciate the commenters' support.

Comment: Other commenters opposed CMS' proposal. A commenter stated that ICD–10–PCS procedure codes that describe the open insertion of a feeding device should be designated as O.R. procedures because they require operating room resources with general anesthesia, and involve incision through the abdominal wall and into the peritoneal cavity with direct visualization. The commenter noted that these procedures may be performed as standalone procedures in patients who are unable to have feeding tubes placed by percutaneous or percutaneous endoscopic approaches because of anatomy, prior surgeries, and adhesions. Another commenter stated that open feeding tube insertions are associated with higher resource use, are prone to more complications, have higher mortality rates, and can have extended recovery times and these procedures should have an OR designation to accurately reflect the resource use for the patient.

Response: We appreciate the commenters' feedback and concern. In response to the comment that these procedures may be performed as standalone procedures in patients who are unable to have feeding tubes placed by percutaneous or percutaneous endoscopic approaches, our clinical advisors note there may be instances when performing any procedure is best done in the setting of an operative room using general anesthesia. However, when looking more broadly at the procedures being described, and the manner in which these procedures are most often performed and their associated resource use our clinical advisors believe that the open insertion of a feeding device in the gastrointestinal system do not warrant an O.R. designation. They noted that these procedures, when performed during a hospitalization, are typically in conjunction with another O.R. procedure and maintain that procedures that describe the open insertion of a feeding device into the esophagus, stomach, small intestine, duodenum, jejunum and ileum are all clinically aligned. Accordingly, our clinical advisors state procedures that describe the open insertion of a feeding device in the gastrointestinal system should all have the same non-O.R. designation in the ICD–10 MS–DRGs Version 39 for coherence.

After consideration of the public comments we received, for the reasons stated, we are finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure code 0DHA0UZ for FY 2022, without modification. We are also finalizing our proposal to change the designation of ICD–10–PCS procedure code 0DH60UZ from O.R. procedure to non-O.R. procedure, without modification, effective October 1, 2021.

(15) Laparoscopic Insertion of Feeding Tube

One requestor identified ICD–10–PCS procedure codes 0DH64UZ (Insertion of feeding device into stomach, percutaneous endoscopic approach) and 0DHA4UZ (Insertion of feeding device into jejunum, percutaneous endoscopic approach) that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor stated the procedures describing the percutaneous endoscopic insertion of a feeding device into the stomach or the jejunum should be designated as O.R. procedures because these procedures are performed in the operating room under general anesthesia. The requestor stated all laparoscopic procedures, regardless if they are diagnostic or therapeutic, should be classified as O.R. procedures to compensate for operating room resources.

In the proposed rule, we stated our analysis of this issue confirmed that in the ICD–10 MS–DRG Version 38.1 Definitions Manual, 0DH64UZ and 0DHA4UZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. We stated in reviewing this request, we also identified the following four related codes:

ICD-10-PCS Code	Code Description
0DH54UZ	Insertion of feeding device into esophagus, percutaneous endoscopic approach
0DH84UZ	Insertion of feeding device into small intestine, percutaneous endoscopic approach
0DH94UZ	Insertion of feeding device into duodenum, percutaneous endoscopic approach
0DHB4UZ	Insertion of feeding device into ileum, percutaneous endoscopic approach

In the ICD–10 MS–DRGs Version 38.1, these four ICD–10–PCS codes are currently recognized as non-O.R. procedures for purposes of MS–DRG assignment. We stated in the proposed rule that our clinical advisors reviewed this request and did not agree that unilaterally all laparoscopic procedures should be designated as O.R. procedures. We stated that while the procedural approach is an important consideration in the designation of a procedure, there are other clinical factors such as the site of procedure, the procedure complexity, and resource utilization that should also be considered. In this regard, our clinical advisors indicated that codes 0DH64UZ and 0DHA4UZ describing the percutaneous endoscopic insertion of a feeding device into the stomach or the jejunum, do not require the resources of an operating room, are not surgical in nature, and are generally performed in the outpatient setting. The percutaneous endoscopic insertion of a feeding device also does not require general anesthesia. As opposed to being rendered unconscious, patients can receive a local anesthetic (usually a lidocaine spray), an intravenous (IV) pain reliever, and a mild sedative if needed. Patients receiving these devices usually return home the same day after placement, unless they are in the hospital for treatment of another condition.

Our clinical advisors stated the percutaneous endoscopic insertion of a feeding device into the stomach or the jejunum is comparable to the related ICD–10–PCS procedure codes that describe the insertion of feeding devices of other gastrointestinal system body parts that are currently designated as non-O.R. procedures. We stated our clinical advisors believed all procedures that describe the percutaneous endoscopic insertion of a feeding device in the gastrointestinal system should continue to have the same non-O.R. designation in the ICD–10 MS–DRGs Version 39 for coherence. Therefore, for the reasons discussed, we proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0DH64UZ and 0DHA4UZ.

Comment: A commenter supported CMS' proposal and stated they agreed that all procedures that describe the percutaneous endoscopic insertion of a feeding device in the gastrointestinal system should continue to have the same non-O.R. designation.

Response: We appreciate the commenters' support.

Comment: Other commenters opposed CMS' proposal. A commenter stated that ICD–10–PCS procedure codes that describe the percutaneous endoscopic insertion of a feeding device should be designated as O.R. procedures. This commenter stated that laparoscopic procedures, whether performed inpatient or outpatient, are indeed surgical procedures which require general anesthesia, have increased procedural risks, and require high skill and specialized equipment. The commenter stated that when necessitated during inpatient stays, even if infrequent, providers should be compensated for operating room resources. Another commenter stated that these procedures require the use of an operating room and should be classified in a manner that reflects the resources expended by the facility in the care and treatment of the patient.

Response: We appreciate the commenters' feedback and concern. Our clinical advisors reviewed the commenters' concerns and continue to state the percutaneous endoscopic insertion of a feeding device into the stomach or the jejunum, does not require the resources of an operating room or general anesthesia. Our advisors state these procedures are not surgical in nature, and because treatment practices have shifted are generally performed in the outpatient setting. When performed in the inpatient setting, patients are generally in the hospital for the treatment of another condition as opposed to the need for operating room resources in an inpatient setting. Accordingly, when considering clinical factors such as the site of procedure, the procedure complexity, and resource utilization, when performed in the inpatient setting, they believe the non-O.R. designation of procedure codes describing the percutaneous endoscopic insertion of a feeding device is supported.

Therefore, after consideration of the public comments we received, we are finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0DH64UZ and 0DHA4UZ, without modification, for FY 2022.

(16) Endoscopic Fragmentation and Extirpation of Matter of Urinary Tract

As discussed in the proposed rule, one requestor sent two separate but related requests related to endoscopic procedures performed in the urinary system. With regard to the first request, the requestor identified six ICD–10–PCS procedure codes that describe endoscopic fragmentation in the kidney pelvis, ureter, bladder, and bladder neck that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The six procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0TF38ZZ	Fragmentation in right kidney pelvis, via natural or artificial opening, endoscopic
0TF48ZZ	Fragmentation in left kidney pelvis, via natural or artificial opening, endoscopic
0TF68ZZ	Fragmentation in right ureter, via natural or artificial opening, endoscopic
0TF78ZZ	Fragmentation in left ureter, via natural or artificial opening, endoscopic
0TFB8ZZ	Fragmentation in bladder, via natural or artificial opening, endoscopic
0TFC8ZZ	Fragmentation in bladder neck, via natural or artificial opening, endoscopic

The requestor stated that these procedures should be designated as O.R. procedures because procedures such as the endoscopic fragmentation of calculi within the kidney pelvis, ureter, bladder, and bladder neck are performed in the operating room under anesthesia. The requestor stated that procedures that describe the endoscopic extirpation of calculi from the kidney pelvis or ureter use comparable resources, and are designated as O.R. procedures. Therefore, the requestor asserted it is reasonable that procedure codes that describe endoscopic fragmentation in kidney pelvis, ureter, bladder, and bladder neck also be designated as O.R. procedures.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0TF38ZZ, 0TF48ZZ, 0TF68ZZ, 0TF78ZZ, 0TFB8ZZ, and 0TFC8ZZ are designated as non-O.R. procedures for purposes of MS–DRG assignment. We stated in the proposed rule that our clinical advisors reviewed this issue and disagreed that procedures describing the endoscopic fragmentation of calculi within the kidney pelvis, ureter, bladder, and bladder neck are typically performed in the operating room. We stated that in endoscopic fragmentation procedures in the kidney pelvis, ureter, bladder, and bladder neck, the scope is passed through a natural or artificial orifice. The procedure is not surgical in nature and involves no skin incisions. With advancements in scope size, deflection capabilities, video imaging, and instrumentation, many patients now have these endoscopic urinary procedures performed in an outpatient setting, instead of the inpatient setting. Therefore, we proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0TF38ZZ, 0TF48ZZ, 0TF68ZZ, 0TF78ZZ, 0TFB8ZZ, and 0TFC8ZZ.

In the second request, the requestor also identified two ICD–10–PCS procedure codes that describe endoscopic extirpation of matter from the bladder and bladder neck that the requestor stated are also currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The two procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0TCB8ZZ	Extirpation of matter from bladder via natural or artificial opening, endoscopic
0TCC8ZZ	Extirpation of matter from bladder neck via natural or artificial opening, endoscopic

The requestor stated that these procedures also should be designated as O.R. procedures because they performed in the operating room under anesthesia.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0TCB8ZZ and 0TCC8ZZ are currently designated as a non-O.R. procedure for purposes of MS–DRG assignment. As indicated in the proposed rule, in response to the second request to designate 0TCB8ZZ and 0TCC8ZZ as O.R. procedures and in response to the requestor's suggestion that resource consumption is comparable in procedures describing endoscopic fragmentation in the urinary system and procedures describing the endoscopic extirpation in the urinary system, we examined the following procedure codes:

ICD-10-PCS Code	Code Description
0TC08ZZ	Extirpation of matter from right kidney, via natural or artificial opening endoscopic
0TC18ZZ	Extirpation of matter from left kidney, via natural or artificial opening endoscopic
0TC38ZZ	Extirpation of matter from right kidney pelvis, via natural or artificial opening endoscopic
0TC48ZZ	Extirpation of matter from left kidney pelvis, via natural or artificial opening endoscopic
0TC68ZZ	Extirpation of matter from right ureter, via natural or artificial opening endoscopic
0TC78ZZ	Extirpation of matter from left ureter, via natural or artificial opening endoscopic

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In the ICD–10 MS–DRG Version 38.1 Definitions Manual, these six ICD–10–PCS procedure codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment. We stated in the proposed rule that our clinical advisors indicated that these procedures are not surgical in nature. In endoscopic extirpation procedures, the scope enters the urinary tract through the urethra, which is the tube that carries urine out of the body, or through an artificial orifice. Our clinical advisors further stated the urinary system is one conduit so the scope continues to pass through the urethra, bladder, and into the ureter or kidney (if necessary) to access the stone. For that reason, we stated the procedures describing endoscopic extirpation from a urinary body part should all have the same non-O.R. designation in the ICD–10 MS–DRGs Version 39 for coherence.

Therefore, we proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0TCB8ZZ and 0TCC8ZZ. We also proposed to remove ICD–10–PCS procedure codes 0TC08ZZ, 0TC18ZZ, 0TC38ZZ, 0TC48ZZ, 0TC68ZZ, and 0TC78ZZ from the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. We stated in the proposed rule that, under this proposal, these procedures would no longer impact MS–DRG assignment.

Comment: Commenters supported CMS' proposal. A commenter stated they supported maintaining the non-O.R. designation of procedure codes describing fragmentation in the kidney pelvis, ureter, bladder, and bladder neck via natural or artificial opening endoscopic approach. This commenter supported maintaining the non-O.R. designation of the procedure codes describing endoscopic extirpation of matter from the bladder and bladder neck and removing six procedure codes describing endoscopic extirpation of matter from the kidney, kidney pelvis, and ureter from the O.R. procedure list. This commenter stated they agreed that procedures describing endoscopic extirpation from a urinary body part should all have the same non-O.R. designation.

Response: We appreciate the commenters' support.

Comment: Other commenters opposed CMS' proposal. These commenters stated endoscopic kidney and ureter procedures traverse narrow tubular structures and require the operating room with specialized equipment, positioning, image-guidance, and general anesthesia to obtain the surgical precision and satisfactory pain control that cannot be provided at the bedside. A commenter stated that although providers attempt to manage conditions that might warrant the performance of these procedures in the outpatient setting, some patients fail outpatient preventative measures and require both medical and surgical interventions in an inpatient setting.

Response: We appreciate the commenters' feedback and concern.

Our clinical advisors reviewed the commenters' concerns and state with development of better instrumentation and surgical techniques, many patients now have endoscopic fragmentation procedures and endoscopic extirpation procedures performed in an outpatient setting. In response to the comment that these procedures cannot be provided at the bedside, we wish to clarify the designation of a procedure as a non-O.R. procedure is not limited to procedures that can be performed at the patient's bedside. While the site in which the procedure is performed and the procedural approach are important considerations in the designation of a procedure, there are other clinical factors such as procedure complexity, resource utilization, and need for anesthesia administration that should also be considered. In this regard, our clinical advisors state endoscopic fragmentation procedures and endoscopic extirpation procedures are not surgical in nature, because treatment practices have shifted and they do not generally require the resources of an operating room or general anesthesia in an inpatient setting.

After consideration of the public comments we received, for the reasons stated, we are, without modification, (1) finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0TF38ZZ, 0TF48ZZ, 0TF68ZZ, 0TF78ZZ, 0TFB8ZZ, and 0TFC8ZZ for FY 2022 and (2) finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0TCB8ZZ and 0TCC8ZZ for FY 2022. We are also finalizing our proposal to change the designation of ICD–10–PCS procedure codes 0TC08ZZ, 0TC18ZZ, 0TC38ZZ, 0TC48ZZ, 0TC68ZZ, and 0TC78ZZ from O.R. procedures to non-O.R. procedures, without modification, effective October 1, 2021.

(17) Endoscopic Removal of Ureteral Stent

One requestor identified ICD–10–PCS procedure code 0TP98DZ (Removal of intraluminal device from ureter, via natural or artificial opening endoscopic) that the requestor stated is not recognized as an O.R. procedure for

purposes of MS–DRG assignment. The requestor suggested that this procedure warrants an O.R. designation because the procedure code describes a procedure that is performed in the operating room with anesthesia. The requestor stated that while most ureteral stents can be removed by string, some complicated cases require endoscopic removal using forceps in the operating room under general anesthesia and may be performed during inpatient stays precipitated by severe urinary tract infection, sepsis, or urinary obstructions. The requestor asserted that procedure codes for insertion of ureteral stent(s) via a ureteroscopic, endoscopic approach have been justifiably designated as O.R. procedures because they are performed in the O.R. under anesthesia. Therefore, the requestor suggested it is reasonable for endoscopic removal of the stent to be designated with OR procedure status to compensate for operating room resources and anesthesia.

We stated in the proposed rule that our clinical advisors reviewed this procedure and did not agree that it warrants an O.R. designation. They noted that this procedure is generally not the focus of the admission when it is performed and does not reflect the technical complexity or resource intensity in comparison to other procedures that are designated as O.R. procedures. Therefore, we proposed to maintain the current non-O.R. designation for procedure code 0TP98DZ for FY 2022.

Comment: Commenters supported our proposal to maintain the non-O.R. designation for procedure code 0TP98DZ.

Response: We appreciate the commenters' support.

Comment: A commenter did not support our proposal based on the rationale provided. According to the commenter, patients may be admitted with sepsis and/or urinary tract infections associated with ureteral stents and require joint focuses of treatment consisting of removal of a stent(s) and intravenous antibiotics. The commenter stated that patients who require stent removal during hospitalization are those who have chronic diagnoses, altered anatomy, or encrusted stents that prevent removal from being performed elsewhere.

Response: Our clinical advisors maintain that generally, the procedure to remove a ureteral stent endoscopically is not the focus or driver of resources for an inpatient admission. With respect to patients who may be admitted with or acquire an infection during the hospitalization, it is understood that these patients typically consume additional resources, however, our clinical advisors do not believe that the endoscopic removal of a ureteral stent is a contributing factor. For those patients who have a chronic diagnosis, altered anatomy or an encrusted stent requiring stent removal specifically in an inpatient setting, we believe additional analysis may be advantageous to determine if a subset of the claims reporting these conditions warrant any modifications to the GROUPER logic. However, the commenter did not provide a list of the specific ICD–10–CM diagnoses describing these conditions for CMS to consider in its analysis for FY 2022. We intend to work with the commenter and examine this issue for consideration in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation for procedure code 0TP98DZ, effective October 1, 2021.

(18) Endoscopic/Transorifice Inspection of Ureter

One requestor identified ICD–10–PCS procedure code 0TJ98ZZ (Inspection of ureter, via natural or artificial opening endoscopic), that describes procedures involving endoscopic viewing of the ureter that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment.

The requestor stated this ureteroscopy procedure is performed in the operating room with anesthesia. According to the requestor, the inspection of ureter procedure code is assigned when obstruction is found during the ureteroscopy and procedures to break up (fragmentation), remove calculi (extirpation), or place a ureteral stent cannot be performed.

In the proposed rule we stated that our clinical advisors reviewed this procedure and disagree that it warrants an O.R. designation. They noted that this procedure typically does not require hospitalization and is generally not the reason for the patient's admission since it is often performed in connection with another O.R. procedure when it is performed. Therefore, we proposed to maintain the current non-O.R. designation for procedure code 0TJ98ZZ for FY 2022.

Comment: Commenters supported our proposal to maintain the non-O.R. designation for procedure code 0TJ98ZZ.

Response: We appreciate the commenters' support.

Comment: A commenter did not support our proposal to maintain the non-O.R. designation for procedure code 0TJ98ZZ based on the rationale that this procedure typically does not require hospitalization and is generally not the reason for the patient's admission since it is often performed in connection with another O.R. procedure. According to the commenter, whether or not a procedure is most often performed as an outpatient should not be the determining factor for designating O.R. status.

Response: Our clinical advisors maintain that typically, this procedure is not the basis for an inpatient admission and as noted earlier in this section, when we state a current non-O.R. procedure is typically performed in conjunction with another O.R. procedure, we are indicating that there is generally another O.R. procedure reported on the claim that is primarily responsible for impacting the utilization of resources for that admission. We wish to clarify that statements indicating a procedure is most often performed as an outpatient or in an outpatient setting are not the single determining factor in our proposals to maintain or modify the designation of a procedure code from O.R. to non-O.R. or vice versa, rather, the proposals set forth in rulemaking are based on a combination of clinical judgment and data, when applicable.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation for procedure code 0TJ98ZZ, without modification, effective October 1, 2021.

(19) Endoscopic Biopsy of Ureter and Kidney

One requestor identified six ICD–10–PCS procedure codes that describe endoscopic biopsy procedures performed on the ureter and kidney structures that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. According to the requestor, regardless of whether it is a diagnostic or therapeutic procedure, these procedures should be designated as O.R. procedures because the procedures utilize operating room, anesthesia and recovery room resources. The requestor stated that after the surgeon places the scope into the bladder that ureteral orifices must be identified and instruments carefully navigated to obtain excisional biopsies from within the ureter or further within the kidney. The six procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0TB08ZX	Excision of right kidney, via natural or artificial opening, endoscopic, diagnostic
0TB18ZX	Excision of left kidney, via natural or artificial opening, endoscopic, diagnostic
0TB38ZX	Excision of right kidney pelvis, via natural or artificial opening, endoscopic, diagnostic
0TB48ZX	Excision of left kidney pelvis, via natural or artificial opening, endoscopic, diagnostic
0TB68ZX	Excision of right ureter, via natural or artificial opening, endoscopic, diagnostic
0TB78ZX	Excision of left ureter, via natural or artificial opening, endoscopic, diagnostic

In the proposed rule we noted that under the ICD–10–PCS procedure classification, biopsy procedures are identified by the 7th digit qualifier value ''diagnostic'' in the code description.

We also noted that our clinical advisors do not agree that endoscopic biopsy procedures performed on the ureter and kidney structures warrant an O.R. designation. They stated these procedures are typically not the focus for the patient's admission and are frequently performed in conjunction with another O.R. procedure. Therefore, we proposed to maintain the current non-O.R. designation for procedure codes 0TB08ZX, 0TB18ZX, 0TB38ZX, 0TB48ZX, 0TB68ZX, and 0TB78ZX for FY 2022.

Comment: Commenters supported our proposal to maintain the non-O.R. designation for procedure codes 0TB08ZX, 0TB18ZX, 0TB38ZX, 0TB48ZX, 0TB68ZX, 0TB78ZX.

Response: We appreciate the commenters' support.

Comment: A commenter did not support our proposal. According to the commenter, urinary obstructions and associated urinary tract infections with or without sepsis can necessitate inpatient admissions, and abnormalities on imaging can raise suspicion for malignancy requiring biopsy for diagnosis and treatment. The commenter stated that when these procedures are standalone procedures performed during inpatient hospitalizations, they warrant O.R. procedure status for the same reasons as the procedures describing endoscopic fragmentation or extirpation of the urinary tract described previously.

Response: We appreciate the commenter's feedback. Similar to the reasons discussed for procedures describing the endoscopic fragmentation or extirpation of the urinary tract, our clinical advisors maintained that with the development of better instrumentation and surgical techniques, many patients now have endoscopic procedures involving urinary tract structures performed in an outpatient setting. In addition, they stated that these procedures are not surgical in nature.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation for procedure codes 0TB08ZX, 0TB18ZX, 0TB38ZX, 0TB48ZX, 0TB68ZX, and 0TB78ZX, without modification, effective October 1, 2021.

(20) Transorifice Insertion of Ureteral Stent

One requestor identified three ICD–10–PCS procedure codes that the requestor stated are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor suggested that the procedure described by these procedure codes warrants an O.R. designation because it involves the insertion of an indwelling ureteral stent through a nephrostomy with image-guidance in the interventional radiology suite. According to the requestor, image-guided technology now allows placement of ureteral stents through nephrostomy tracts. The requestor stated this procedure may or may not be performed in the operating room, however, it involves placement of device(s), interventional radiology resources, sedation, and continuous monitoring of vital signs. The three procedure codes are shown in the following table.

ICD-10-PCS Code	Code Description
0T767DZ	Dilation of right ureter with intraluminal device, via natural or artificial opening
0T777DZ	Dilation of left ureter with intraluminal device, via natural or artificial opening
0T787DZ	Dilation of bilateral ureters with intraluminal device, via natural or artificial opening

In the proposed rule we stated that our clinical advisors reviewed this request and do not agree that this procedure warrants an O.R. designation. They noted that this procedure is not surgical in nature, does not require the resources of an operating room and is not a technically complex procedure requiring increased hospital resources. Therefore, we proposed to maintain the current non-O.R. designation for procedure codes 0T767DZ, 0T777DZ, and 0T787DZ for FY 2022.

Comment: Commenters supported our proposal to maintain the non-O.R. designation for procedure codes 0T767DZ, 0T777DZ, and 0T787DZ.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation for procedure codes 0T767DZ, 0T777DZ, and 0T787DZ, without modification, effective October 1, 2021.

(21) Percutaneous Insertion of Ureteral Stent

One requestor identified three ICD–10–PCS procedure codes that the requestor stated are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor suggested that the procedure described by these procedure codes warrants an O.R. designation because the procedure is typically performed following a failed ureteral stent insertion procedure in the operating room, which can only be reported as a cystoscopy or ureteroscopy, neither of which are designated as O.R. procedures. According to the requestor, percutaneous ureteral stenting through the abdominal wall is subsequently performed in an interventional radiology suite with image-guidance, sedation, and continuous vital sign monitoring. The three procedure codes are shown in the following table.

ICD-10-PCS Code	Code Description
0T763DZ	Dilation of right ureter with intraluminal device, percutaneous approach
0T773DZ	Dilation of left ureter with intraluminal device, percutaneous approach
0T783DZ	Dilation of bilateral ureters with intraluminal device, percutaneous approach

In the proposed rule we stated that our clinical advisors reviewed this request and do not agree that the procedure warrants an O.R. designation. They noted that this procedure is not surgical in nature, does not involve technical complexity or require the resources of an operating room. Therefore, we proposed to maintain the current non-O.R. designation for procedure codes 0T763DZ, 0T773DZ, and 0T783DZ for FY 2022.

Comment: Commenters supported our proposal to maintain the non-O.R. designation for procedure codes 0T763DZ, 0T773DZ, and 0T783DZ.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation for procedure codes 0T763DZ, 0T773DZ, and 0T783DZ, without modification, effective October 1, 2021.

(22) Endoscopic Dilation of Urethra

One requestor identified ICD–10–PCS procedure code 0T7D8DZ (Dilation of urethra with intraluminal device, via natural or artificial opening endoscopic) that the requestor stated is not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor suggested that this procedure warrants an O.R. designation because the procedure code describes a procedure that utilizes the UroLift® System, a minimally invasive technology to treat lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). According to the requestor, the technology is placed endoscopically within the prostatic urethra in the operating room under anesthesia.

In the proposed rule we stated that our clinical advisors reviewed this request and do not agree that the procedure warrants an O.R. designation. They noted that this procedure is performed without incision, resection or thermal injury to the prostate and is primarily performed in the outpatient setting. It is generally not the cause for the patient's admission and utilization of resources when it is performed. Therefore, we proposed to maintain the current non-O.R. designation for procedure code 0T7D8DZ for FY 2022.

Comment: Commenters supported our proposal to maintain the non-O.R. designation for procedure code 0T7D8DZ.

Response: We appreciate the commenters' support.

Comment: A commenter did not support our proposal to maintain the non-O.R. designation for procedure code 0T7D8DZ based on the rationale that this procedure is primarily performed in the outpatient setting and is generally not the cause for the patient's admission and utilization of resources. According to the commenter, whether or not a procedure is most often performed as an outpatient should not be the determining factor in O.R status. The commenter asserted that in its review of procedures currently assigned to MS–DRGs 671 and 672, the procedure described by procedure code 0T7D8DZ utilizes comparable O.R. resources.

Response: We thank the commenter for their feedback. Our clinical advisors maintain that typically, this procedure is not the basis for an inpatient admission and if performed, it does not increase the consumption of hospital resources to warrant O.R. status. With regard to the list of procedures currently assigned to MS–DRGs 671 and 672 and the assertion that code 0T7D8DZ utilizes comparable O.R. resources, as stated in previous rulemaking, as well as, the preamble of the FY 2022 IPPS/LTCH PPS proposed rule and this final rule, we are in the process of reviewing prior stakeholder feedback on criteria and factors to consider on what constitutes a procedure being designated as O.R versus non-O.R. as a component of our broader comprehensive procedure code review. We are allowing additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review considering the PHE, and to develop our proposed methodology. Therefore, we will be examining all the procedures currently assigned to MS–DRGs 671 and 672 in connection with that process and discuss if modifications to the designation of code 0T7D8DZ are warranted.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation for procedure code 0T7D8DZ, without modification, effective October 1, 2021.

(23) Open Repair of Scrotum

One requestor identified ICD–10–PCS procedure code 0VQ50ZZ (Repair scrotum, open approach) that the requestor stated is not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor suggested that this procedure warrants an O.R. designation because it involves repair of scrotal tissue deeper than the skin with direct visualization and utilizes general anesthesia in the operating room.

We noted in the proposed rule that our clinical advisors do not agree that open repair of the scrotum merits an O.R. designation. They stated this procedure would not typically require the resources of an operating room and would generally not be a contributing factor impacting hospital resource use during the patient's admission when it is performed. Therefore, we proposed to maintain the current non-O.R. designation for procedure code 0VQ50ZZ for FY 2022.

Comment: Commenters supported our proposal to maintain the non-O.R. designation for procedure code 0VQ50ZZ.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation for procedure code 0VQ50ZZ, without modification, effective October 1, 2021.

(24) Open Drainage of Vestibular Gland

One requestor identified ICD–10–PCS procedure code 0U9L0ZZ (Drainage of vestibular gland, open approach) that describes a procedure commonly performed for the treatment of an abscess that the requestor stated is performed in the operating room under general anesthesia and therefore warrants an O.R designation. The requestor stated this procedure is comparable to the procedure described by procedure code 0UBL0ZZ (Excision of vestibular gland, open approach) which is currently designated as an O.R. procedure.

We stated in the proposed rule that during our review of procedure code 0U9L0ZZ, we also examined procedure codes 0U9L0ZX (Drainage of vestibular gland, open approach, diagnostic), 0U9LXZX (Drainage of vestibular gland, external approach, diagnostic), and 0UBL0ZZ. Separately, we reviewed procedure code 0T9D0ZZ (Drainage of urethra, open approach) because it represents the male equivalent of the female procedure described by procedure code 0U9L0ZZ.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0T9D0ZZ, 0U9L0ZX, 0U9LXZX, and 0UBL0ZZ are currently designated as O.R. procedures, however, procedure code 0U9L0ZZ is not recognized as an O.R. procedure for purposes of MS–DRG assignment. In the proposed rule we stated that we examined procedure code 0U9L0ZZ and do not believe this drainage procedure warrants an O.R. designation, nor do we agree that this drainage of the vestibular gland procedure (0U9L0ZZ) is comparable to an excision of the vestibular gland procedure (0UBL0ZZ), which is currently designated as an O.R. procedure.

In the ICD–10–PCS classification, drainage is defined as taking or letting out fluids and/or gases from a body part and excision is defined as cutting out or off, without replacement, a portion of a body part. Therefore, the classification specifically defines and distinguishes the underlying objectives of each distinct procedure. In the proposed rule we noted that our clinical advisors stated a drainage procedure is frequently performed in the outpatient setting and is generally not the cause for the patient's admission and utilization of resources when it is performed. Drainage of the vestibular gland, also known as Bartholin's glands, is typically indicated when a cyst or abscess is present and may or may not involve the placement of a Word catheter. Conversely, excision of the vestibular gland is not considered an office-based procedure and is generally reserved for a vulvar mass or for patients who have not responded to more conservative attempts to create a drainage tract. In addition, after review, our clinical advisors recommended changing the O.R. status for procedure codes 0U9L0ZX and 0U9LXZX from O.R. to non-O.R. for similar reasons. These procedures do not typically require the resources of an operating room.

Therefore, we proposed to remove procedure codes 0U9L0ZX and 0U9LXZX from the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E- Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures and noted that under this proposal, these procedure codes would no longer impact MS–DRG assignment. We refer the reader to section II.D.10 of the preamble of the proposed rule and this final rule for further discussion related to procedure code 0T9D0ZZ.

Comment: Commenters supported our proposal to maintain the non-O.R. designation of procedure code 0U9L0ZZ and to change the designation of procedure codes 0U9L0ZX and 0U9LXZX from O.R. to non-O.R.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation of procedure code 0U9L0ZZ and to change the designation of procedure codes 0U9L0ZX and 0U9LXZX from O.R. to non-O.R., effective October 1, 2021.

(25) Transvaginal Repair of Vagina

One requestor identified ICD–10–PCS procedure code 0UQG7ZZ (Repair vagina, via natural or artificial opening) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor stated that procedures described by this code such as the non-obstetric transvaginal repair of the vaginal cuff and the non-obstetric transvaginal repair of vaginal lacerations should be designated as O.R. procedures because these procedures are performed in the operating room under general anesthesia. The requestor noted procedure codes 0USG7ZZ (Reposition vagina, via natural or artificial opening), 0UBG7ZZ (Excision of vagina, via natural or artificial opening), and 0UQG8ZZ (Repair vagina, via natural or artificial opening endoscopic) are currently designated as O.R. procedures, therefore procedure code 0UQG7ZZ should also be recognized as an O.R. procedure for purposes of MS–DRG assignment.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure code 0UQG7ZZ is currently designated as a non-O.R. procedure for purposes of MS–DRG assignment. In the proposed rule, we stated that our clinical advisors reviewed this issue and disagreed that a correlation can be made between procedures described as the transvaginal repair of the vagina and the procedures described by ICD–10–PCS codes 0USG7ZZ, 0UBG7ZZ, and 0UQG8ZZ. We stated that the root operation ''repair'' represents a broad range of procedures for restoring the anatomic structure of a body part such as suture of lacerations, while the root operations ''reposition,'' and ''excision'' define procedures with more distinct objectives. Also, the approach ''via natural or artificial opening'', for example, transvaginal, is defined as the entry of instrumentation through a natural or artificial external opening to reach the site of the procedure while the ''via natural or artificial opening endoscopic approach'' is defined as the entry of instrumentation (for example a scope) through a natural or artificial external opening to both reach and visualize the site of the procedure. We stated that our clinical advisors also disagreed that procedures described as the transvaginal repair of the vagina are typically performed in the operating room under general anesthesia. Our clinical advisors stated transvaginal repair can be performed using regional anesthesia, used to numb only the area of the body that requires surgery instead of rendering the patient unconscious. Therefore, for the reasons described, we proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure code 0UQG7ZZ.

Comment: Commenters supported CMS' proposal to maintain the non-O.R. designation of a procedure code describing repair of vagina via natural or artificial opening.

Response: We appreciate the commenters' support.

Comment: Other commenters opposed CMS' proposal to maintain the non-O.R. designation of ICD–10–PCS procedure code 0UQG7ZZ. A commenter stated

procedures such as vaginal cuff revisions must be performed in the operating room under general anesthesia because a sterile surgical environment remains required for surgeons to accomplish this procedure before safely discharging patients. Another commenter stated that transvaginal repair of the vagina is typically an emergent procedure and for the safety of the patient, the procedure is best performed in the operating room under general anesthesia so the patient can stay relaxed. This commenter also stated that when this procedure is performed for indications such as vaginal cuff dehiscence, it is common that a concurrent procedure may be indicated to ensure there was not compromised/ischemic bowel since is imperative that the bowel is kept out of the field while the cuff is closed.

Response: We appreciate the commenters' feedback and concern.

Our clinical advisors reviewed the commenters' concerns and continue to support maintaining the current non-O.R. designation for ICD–10–PCS procedure code 0UQG7ZZ. While our clinical advisors agree that procedures described as the transvaginal repair of the vagina are often performed in conjunction with another O.R. procedure, they do not agree that this procedure warrants an O.R. designation. They stated these procedures are typically not the focus for the patient's admission, and that the other definitive procedures performed with the transvaginal repair of the vagina in the inpatient setting would be considered the principal driver of resource expenditure in those admissions.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure code 0UQG7ZZ, without modification, for FY 2022.

(26) Percutaneous Tunneled Vascular Access Devices

One requestor identified ten ICD–10–PCS procedure codes describing percutaneous insertion of tunneled vascular access devices into various body parts that the requestor stated are not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor suggested that these procedures warrant an O.R. designation because they are placed in an interventional radiology suite or in the operating room under anesthesia. The ten procedure codes are shown in the following table.

ICD-10-PCS Code	Code Description
0JH63XZ	Insertion of tunneled vascular access device into chest subcutaneous tissue and fascia, percutaneous approach
0JH83XZ	Insertion of tunneled vascular access device into abdomen subcutaneous tissue and fascia, percutaneous approach
0JHD3XZ	Insertion of tunneled vascular access device into right upper arm subcutaneous tissue and fascia, percutaneous approach
0JHF3XZ	Insertion of tunneled vascular access device into left upper arm subcutaneous tissue and fascia, percutaneous approach
0JHG3XZ	Insertion of tunneled vascular access device into right lower arm subcutaneous tissue and fascia, percutaneous approach
0JHH3XZ	Insertion of tunneled vascular access device into left lower arm subcutaneous tissue and fascia, percutaneous approach
0JHL3XZ	Insertion of tunneled vascular access device into right upper leg subcutaneous tissue and fascia, percutaneous approach
0JHM3XZ	Insertion of tunneled vascular access device into left upper leg subcutaneous tissue and fascia, percutaneous approach
0JHN3XZ	Insertion of tunneled vascular access device into right lower leg subcutaneous tissue and fascia, percutaneous approach
0JHP3XZ	Insertion of tunneled vascular access device into left lower leg subcutaneous tissue and fascia, percutaneous approach

According to the requestor, it does not make sense for tunneled vascular access devices to group to procedural MS–DRGs in limited circumstances as is the case currently with the logic in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). The requestor stated that these procedures should be grouping to procedural MS–DRGs across all MDCs.

In the proposed rule we noted that we have addressed requests related to these procedures in previous rulemaking (85 FR 58511 through 58517). We also stated that our clinical advisors reviewed this request and disagreed that procedures performed to insert a tunneled vascular access device should group to procedural MS–DRGs across all MDCs. They stated that these percutaneous procedures are generally performed in the outpatient setting and when performed during a hospitalization, they are frequently performed in combination with another O.R. procedure. Therefore, we proposed to maintain the current non-O.R. status

for the ten procedure codes listed previously for FY 2022.

Comment: Commenters supported our proposal to maintain the non-O.R. designation for procedure codes 0JH63XZ, 0JH83XZ, 0JHD3XZ, 0JHF3XZ, 0JHG3XZ, 0JHH3XZ, 0JHL3XZ, 0JHM3XZ, 0JHN3XZ and 0JHP3XZ.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. designation for procedure codes 0JH63XZ, 0JH83XZ, 0JHD3XZ, 0JHF3XZ, 0JHG3XZ, 0JHH3XZ, 0JHL3XZ, 0JHM3XZ, 0JHN3XZ and 0JHP3XZ, effective October 1, 2021.

12. Changes to the MS–DRG Diagnosis Codes for FY 2022

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as a MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when assigning severity levels to new codes and when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 final rule, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16- (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed severity level designation changes for FY 2020.

We discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554) that we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking. The nine guiding principles are as follows:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for a complete discussion of our response to public comments regarding the nine guiding principles. We continue to solicit feedback regarding these guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. When providing additional feedback or comments, we encourage the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code.

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175), for new diagnosis codes approved for FY 2022, consistent with our annual process for designating a severity level (MCC, CC or NonCC) for new diagnosis codes, we first review the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We noted that this process does not automatically result in the new diagnosis code having the same designation as the predecessor code. We refer the reader to II.D.13 of this final rule for the discussion of the proposed changes to the ICD–10–CM and ICD–10–PCS coding systems for FY 2022.

In the FY 2022 IPPS/LTCH PPS proposed rule, we noted that we received several requests to change the severity level designations of specific ICD–10–CM diagnosis codes. We stated our clinical advisors believed it was appropriate to consider these requests in connection with our continued comprehensive CC/MCC analysis in future rulemaking, rather than proposing to change the designation of individual ICD–10–CM diagnosis codes at this time. As discussed in the proposed rule and noted earlier in this section, we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles. We will consider these individual requests received for changes to severity level designations as we continue our comprehensive CC/MCC analysis and will provide more detail in future rulemaking.

Comment: A commenter stated they agreed with the decision by CMS to withhold its recommendations pending a complete discussion of how the comprehensive CC/MCC analysis in future rulemaking is to be constructed. This commenter also stated they appreciated CMS' publication of the guiding principles of what should constitute a CC or MCC.

Response: We appreciate the commenters'' support. In response to the comment that the guiding principles indicate what should constitute a CC or MCC, as noted in the FY 2021 IPPS/LTCH PPS final rule, we do not believe the nine guiding principles would be mostly applicable, or only applicable, to CC or MCC conditions. In applying the nine guiding principles in our review of the appropriate severity level designation, the intention is not to require that a diagnosis code satisfy each principle, or a specific number of principles in assessing whether to designate a secondary diagnosis code as a NonCC versus a CC versus a MCC. Rather, the severity level determinations would be based on the consideration of the clinical factors captured by these principles as well as the empirical analysis of the additional resources associated with the secondary diagnosis.

Comment: Other commenters expressed their willingness to partner with CMS to provide their expertise to assist in the continuation of a comprehensive CC/MCC analysis. These commenters requested that CMS post another secondary diagnosis impact on resource use file so that the public can determine how individual ICD–10–CM diagnosis codes affect resource use when reported as secondary diagnoses. A commenter stated providing this information will help prepare the public and inform the feedback and advice summitted by the public in the IPPS comment periods of future rulemaking.

Response: While CMS has already convened an internal workgroup comprised of clinicians, consultants, coding specialists and other policy analysts, we welcome additional public feedback. Commenters can continue to submit their recommendations to the following email address: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2021.

In response to the request that CMS make an updated impact on resource use file available, we note that in May 2021, we made an updated impact on resource use file available so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 MedPAR file and the FY 2020 MedPAR file. The link to this file is posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

c. Potential Change to Severity Level Designation for Unspecified Diagnosis Codes for FY 2022

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180), as another interval step as we continue to address the comprehensive review of the severity designations of ICD–10–CM diagnosis codes in which we have been engaged over the past two years, we requested public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we were considering adopting for FY 2022. Specifically, we noted we were considering changing the severity level designation of all ''unspecified'' diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site, effective for FY 2022, after consideration of the public comments we receive in response to the proposed rule.

We noted that according to the ICD–10–CM Official Guidelines for Coding and Reporting, codes titled ''unspecified'' are for use when the information in the medical record is insufficient to assign a more specific code. In our review of severity level designation of the codes in the ICD–10–CM classification, we stated we noted 3,490 ''unspecified'' diagnosis codes designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site with an equivalent severity level designation. For example, ICD–10–CM code L89.003 (Pressure ulcer of unspecified elbow, stage 3) is currently designated as a MCC. In the same code subcategory of L89.0- (Pressure ulcer of elbow), ICD–10–CM codes L89.013 (Pressure ulcer of right elbow, stage 3) and code L89.023 (Pressure ulcer of left elbow, stage 3) are also designed as MCCs.

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described the categorization of diagnoses as an MCC, a CC, or a NonCC, accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. As such, the designation of CC or MCC is intended to account for the increased resources required to address a condition as a secondary diagnosis. The usage of ''unspecified'' diagnosis codes where there are other codes available in that code subcategory that further specify the anatomic site may contribute to and eventually result in less reliable data for researching clinical outcomes. If documentation is not available to code to the highest level of specificity as to the laterality of the condition treated, and an unspecified code is reported by the hospital, it may be harder to quantify in the claims data what additional resources were expended to address that condition in terms of requiring clinical evaluation, therapeutic treatment, diagnostic procedures, extended length of hospital stay, increased nursing care and/or monitoring.

As stated in the proposed rule and previously, we discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554) that we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data, and the application of nine guiding principles, and plan to present the findings and proposals in future rulemaking. As patients present with a variety of diagnoses, in examining the secondary diagnoses, we stated we would consider what additional resources are required, that surpasses those that are already being utilized to address the principal diagnosis and/or other secondary diagnoses that might also be present on the claim. The goal of our comprehensive analysis is to create stratification for reimbursing inpatient hospitalization in the fewest amount of categories with the most explanatory power in a clinically cohesive way. We stated in the FY 2022 proposed rule that we believed more robust claims data

would facilitate this effort to determine the impact on resource use and inform our decision-making in determining the most appropriate CC subclass (NonCC, CC, or MCC) assignment for each diagnosis as a secondary diagnosis. As part of this effort, we solicited comments on adopting a change to the severity level designation of the 3,490 ''unspecified'' diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to a NonCC for FY 2022.

As discussed in the HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS proposed rule (73 FR 49796 through 49803), in proposing the adoption of ICD–10–CM and ICD–10–PCS, we listed that the addition of laterality in ICD–10–CM—specifying which organ or part of the body is involved when the location could be on the right, the left, or could be bilateral, was one of several improvements over ICD–9–CM. We also noted that in comparison to ICD–9–CM, ICD–10–CM diagnosis codes are very specific and that this specificity improves the richness of data for analysis and improves the accuracy of data used for medical research. In the Modifications to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS final rule (74 FR 3328 through 3362), we adopted the ICD–10–CM and ICD–10–PCS as medical data code sets under HIPAA, replacing ICD–9–CM Volumes 1 and 2, and Volume 3 and noted that ICD–10–CM and ICD–10–PCS provide specific diagnosis and treatment information that can improve quality measurements and patient safety, and the evaluation of medical processes and outcomes. We stated in the FY 2022 proposed rule that we continue to believe that reporting the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition would more accurately reflect the health care encounter and improve the reliability and validity of the coded data.

We also stated we believe that changing the severity level for these ''unspecified codes'' as compared to the more specific codes in the same subcategory recognizing laterality would leverage the additional specificity available under the ICD–10 system, by fostering the reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data. However, in consideration of the PHE, and to the extent that some providers may not currently have programs in place that focus on improving documentation, we requested public comments on making this change to the severity level designation for these unspecified ICD–10–CM diagnosis codes for FY 2022.

We refer the reader to table 6P.2a associated with the proposed rule for a detailed list of the diagnosis codes for which we solicited comments on a change in severity level. As noted in the proposed rule, we also made available the data describing the impact on resource use when reported as a secondary diagnosis for all 3,490 ICD–10–CM unspecified diagnosis codes. While these claims data were not used in our identification of the ''unspecified'' diagnosis codes for which there are other codes available in the code subcategory that further specify the anatomic site, as stated in the proposed rule and earlier in this section, these data are consistent with data historically used to mathematically measure impact on resource use for secondary diagnoses, and the data which we plan to use in combination with application of the nine guiding principles as we continue a comprehensive CC/MCC analysis. Therefore, we displayed the data on these unspecified codes in order to facilitate public comment on these potential changes in the severity level designation for these codes.

In Table 6P.2a associated with the proposed rule, column C displays the FY 2020 severity level designation for these diagnosis codes in MS–DRG Grouper Version 37.2. Column D displays CMS' current FY 2021 severity level designation in MS–DRG Grouper Version 38.1 and column E displays the potential changes to the severity level designation that we stated we were considering adopting. Columns F–O show data on the impact on resource use generated using discharge claims from the September 2019 update of the FY 2019 MedPAR file and MS–DRG Grouper Version 37.2. Columns Q–Z show data on the impact on resource use generated using discharge claims from the September 2020 update of the FY 2020 MedPAR file and MS–DRG Grouper Version 38.1.

For further information on the data on the impact on resource use as displayed in Columns F–O and Columns Q–Z, we refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of the methodology utilized to mathematically measure the impact on resource use. Also, as discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts.html* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the data describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session. We note that the supplementary file that was made available for the listening session contains the mathematical data for the impact on resource use generated using claims from the FY 2018 MedPAR file. We have also made available on the CMS website an updated impact on resource use file so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 MedPAR file and the FY 2020 MedPAR file.

This table shows the Version 38.1 ICD–10 MS–DRG categorization of diagnosis codes by severity level.

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Current Categorization of CC Codes (Version 38.1)	
	Number of Codes
MCC	3,278
CC	14,679
NonCC	54,664
Total	72,621

As stated in the proposed rule, we requested public comments on a modification to the Version 38.1 severity level subclass assignments for 4.8 percent of the ICD–10–CM diagnosis codes, potentially effective with the Version 39 ICD–10 MS–DRG MCC/CC list. The following table compares the Version 38.1 ICD–10 MS–DRG MCC/CC list and the potential Version 39 ICD–10 MS–DRG MCC/CC list. There are 17,957 diagnosis codes on the Version 38.1 MCC/CC lists. These potential MCC/CC severity level changes would reduce the number of diagnosis codes on the MCC/CC lists to 14,467 (2,771 + 11,696).

POTENTIAL MCC/CC SUBCLASS MODIFICATIONS						
Severity Level – CC Subclass	**Version 38.1 Severity Level Number of Codes**	**Potential Version 39 Severity Level Number of Codes**	**Percent Change**	**Potential Version 39 Change to MCC subclass, Number of Codes**	**Potential Version 39 Change to CC subclass, Number of Codes**	**Potential Version 39 Change to NonCC subclass, Number of Codes**
MCC	3,278	2,771	-15.5%	N/A	0	507
CC	14,679	11,696	-20.3	0	N/A	2,983
NonCC	54,664	58,154	6.4%	0	0	N/A
Total	**72,621**	**72,621**	**N/A**	**0**	**0**	**3,490**

The net result of these potential changes to the Version 39 ICD–10 MS–DRG MCC/CC list, for the 72,621 diagnosis codes in the ICD–10–CM classification, would be a decrease of 507 (3,278 − 2,771) codes designated as an MCC, a decrease of 2,983 (14,679 − 11,696) codes designated as a CC, and an increase of 3,490 (58,154 − 54,664) codes designated as a NonCC.

The following table compares the Version 38.1 ICD–10 MS–DRG severity level list and the potential Version 39 ICD–10 MS–DRG severity level list by each of the 22 chapters of the ICD–10–CM classification to display how each chapter of ICD–10–CM might be affected by these modifications.

ICD-10-CM Chapter	Version 38.1 MCC+CC Subclass, Number of Codes	Potential Version 39 Change to NonCC subclass, Number of Codes	Potential Version 39 Severity Level Number of Codes	Percent Change
Certain infectious and parasitic diseases (A00-B99)	757	0	757	0%
Neoplasms (C00-D49)	782	31	751	-4.0%
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism (D50-D89)	142	0	142	0%
Endocrine, nutritional and metabolic diseases (E00-E89)	246	0	246	0%
Mental, Behavioral and Neurodevelopmental disorders (F01-F99)	265	0	265	0%
Diseases of the nervous system (G00-G99)	250	6	244	-2.4%
Diseases of the eye and adnexa (H00-H59)	259	62	197	-23.9%
Diseases of the ear and mastoid process (H60-H95)	32	5	27	-15.6%
Diseases of the circulatory system (I00-I99)	709	58	651	-8.2%
Diseases of the respiratory system (J00-J99)	160	0	160	0%
Diseases of the digestive system (K00-K95)	397	0	397	0%
Diseases of the skin and subcutaneous tissue (L00-L99)	323	55	268	-17.0%
Diseases of the musculoskeletal system and connective tissue (M00-M99)	1,414	413	1,001	-29.2%
Diseases of the genitourinary system (N00-N99)	168	2	166	-1.2%
Pregnancy, childbirth and the puerperium (O00-O9A)	652	4	648	-0.6%
Certain conditions originating in the perinatal period (P00-P96)	163	0	163	0%
Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)	252	0	252	0%

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified (R00-R99)	74	0	74	0%
Injury, poisoning and certain other consequences of external causes (S00-T88)	10,867	2,854	8,013	-26.3%
External causes of morbidity (V00-Y99)	0	0	0	0%
Factors influencing health status and contact with health services (Z00-Z99)	44	0	44	0%
Codes for special purposes (U00-U85)	1	0	1	0%
Total	**17,957**	**3,490**	**14,467**	**-19.4%**

As shown in the table, the Diseases of the Musculoskeletal System and Connective Tissue (M00–M99) chapter of ICD–10–CM would have the largest percentage reduction in codes designated as CC/MCC. Twelve chapters would have a zero percentage change to the percentage of codes designated as CC/MCC.

As stated in the proposed rule and previously, we requested public comments on our possible adoption of a change to the severity level designation of these 3,490 ''unspecified'' diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to a NonCC, potentially effective with the Version 39 ICD–10 MS–DRG MCC/CC list. As part of this request, we stated we would be interested in comments regarding whether this modification might present operational challenges and how we might otherwise foster the reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

In this FY 2022 IPPS/LTCH PPS final rule, we present a summation of the comments we received on our possible adoption of a change to the severity level designation of the 3,490 ''unspecified'' diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to a NonCC, potentially effective with the Version 39 ICD–10 MS–DRG MCC/CC list and our responses to those comments. We appreciate commenters for sharing their views and their willingness to support CMS in our efforts to continue a comprehensive CC/MCC analysis.

Comment: Many commenters supported CMS' possible adoption of a change to the severity level designation of the 3,490 ''unspecified'' diagnosis codes to a NonCC when there are more specific codes available in that code subcategory that recognize laterality. Some commenters stated it is reasonable to expect that laterality would be documented in the hospital inpatient setting in most cases. A commenter stated that they agreed that reporting the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition would more accurately reflect the healthcare encounter and improve the reliability and validity of the coded data. This commenter further stated the anticipated benefits of the ICD–10–CM transition (including better data for measuring quality and safety of patient care, assessing patient outcomes, determining disease severity for risk and severity adjustment, and conducting analyses and research) cannot be realized if healthcare encounters are not coded and documented to the highest possible level of specificity. A commenter stated that they appreciated that CMS is considering changing the severity designation of ''unspecified'' diagnosis codes where a more specific code describing laterality is available as they have observed that the presence of these codes in the classification has become a challenge when determining how to code based on vague medical record documentation. Another commenter stated they supported CMS' aim to encourage diagnosis coding to the highest level of specificity available, and stated specifically, if there are codes that can be used to indicate laterality, then those codes should be reported rather than an unspecified code.

Response: We appreciate the commenters' support.

Comment: Other commenters questioned the need for such a change. Commenters stated the use of unspecified codes in reporting diagnoses that describe the patient's condition does not diminish the resources required to care for patients. A commenter requested that CMS provide insight pertaining to how the laterality of the condition impacts the severity of the diagnosis. Another commenter stated the treatment plans developed by providers to address diagnoses remains the same, regardless of the laterality affected. Another commenter stated that the laterality of a condition does not clinically impact the severity of the diagnosis or make it less costly to treat, and that it also does not offer any more value to the reported data.

Response: We appreciate the commenter's' feedback.

To clarify how the concept of laterality is reflected in the claims data and the importance in accurately reporting this information we provide the following examples of diagnosis codes and their impact on resource use as represented in the claims data when reported as a secondary diagnosis.

The following table reflects the impact on resource use data using the September 2019 update of the FY 2019 MedPAR file for diagnosis codes that describe stage 3 pressure ulcers of the hip. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our historical approach to mathematically

evaluate the extent to which the presence of an ICD–10–CM code as a secondary diagnosis resulted in increased hospital resource use, and the explanation of the columns in the table.

ICD-10 CM Diagnosis Code	Code Description	V38.1 Severity Designation	Tota1 Count	Cnt1	C1	Cnt2	C2	Cnt3	C3
L89.203	Pressure ulcer of unspecified hip, stage 3	MCC	108	2	0.75989	11	2.87883	95	2.83683
L89.213	Pressure ulcer of right hip, stage 3	MCC	2,365	19	2.35497	300	2.41460	2,046	3.09379
L89.223	Pressure ulcer of left hip, stage 3	MCC	2,303	28	1.26691	260	2.33631	2,015	3.07005

As shown in the table, the three diagnosis codes that describe stage 3 pressure ulcers of the hip are designated as MCCs in Version 38.1 of the ICD–10 MS–DRGs. When examining diagnosis code L89.213 (Pressure ulcer of right hip, stage 3), the value in column C1is closer to 2.0 than to 1.0. The data suggests that when stage 3 pressure ulcers of the right hip are reported as a secondary diagnosis, the resources involved in caring for these patients are more aligned with a CC than a NonCC or an MCC, as explained in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159). However, when examining diagnosis codes L89.223 (Pressure ulcer of left hip, stage 3) and L89.203 (Pressure ulcer of unspecified hip, stage 3), the C1 values are generally closer to 1, which suggest the resources involved in caring for stage 3 pressure ulcers of the left hip or an unspecified hip are more aligned with a NonCC severity level than a CC or an MCC severity level.

The following table reflects the impact on resource use data using the September 2020 update of the FY 2020 MedPAR file for the same three diagnosis codes.

ICD-10 CM Diagnosis Code	Code Description	V38.1 Severity Designation	Total Count	Cnt1	C1	Cnt2	C2	Cnt3	C3
L89.203	Pressure ulcer of unspecified hip, stage 3	MCC	56	0	-	6	2.21302	50	4.00000
L89.213	Pressure ulcer of right hip, stage 3	MCC	2,012	22	0.91116	232	2.35610	1,758	3.04804
L89.223	Pressure ulcer of left hip, stage 3	MCC	1,969	14	2.16086	220	2.35366	1,735	2.97141

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When examining this data file, we find opposite results. The C1 values for diagnosis code L89.213 (Pressure ulcer of right hip, stage 3) is generally close to 1 and the C2 values for L89.213 and L89.203 (Pressure ulcer of unspecified hip, stage 3) are generally close to 2, both of which suggest the resources involved in caring for stage 3 pressure ulcers of the right hip or an unspecified hip are more aligned with a NonCC severity level than a CC or an MCC severity level. However, when examining diagnosis code L89.223 (Pressure ulcer of left hip, stage 3), the value in column C1 is closer to 2.0, which suggests that when stage 3 pressure ulcers of the left hip are reported as a secondary diagnosis, the resources involved in caring for these patients are more aligned with a CC than either a NonCC or an MCC.

As we have noted in prior rulemaking, these mathematical constructs are used as guides in conjunction with the judgment of our clinical advisors to classify each secondary diagnosis reviewed. We present these data to highlight that when taking laterality into account, the resources expended in caring for certain conditions may not be as equally expressed in the claims data as some commenters may suggest and to demonstrate how reporting the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition could

more accurately reflect the health care encounter and improve the reliability and validity of the coded data the 108 cases and 56 cases that reported a stage 3 pressure ulcer of an unspecified hip as a secondary diagnosis in the FY 2019 and FY 2020 MedPAR file, respectively, may each reflect an opportunity to potentially have reported more specific and valuable data that could be used in evaluating the impact of resource use in the claims data, had the laterality been specified.

We also note that in Table 6P.2a associated with the proposed rule, of the 3,490 diagnosis codes listed, when reviewing the total counts in the data on the impact on resource use generated using discharge claims from the September 2019 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, only 36 and 38 ICD–10–CM codes respectively, were reported in numbers greater than 500 in the claims data. The remaining codes were generally all reported in small numbers. In fact, in as shown in table 6P.2a, 2,772 and 2,767 of these codes were reported zero times in the claims data when reviewing the impact on resource use generated using discharge claims from the September 2019 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, respectively.

As noted in the proposed rule, this consideration of a possible adoption to change the severity level designation of certain unspecified codes was to foster the reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data. These findings demonstrate providers are already appropriately documenting laterality in most instances.

Comment: Other commenters noted that laterality is not one of CMS' long-standing criteria for determining the severity level of a condition. These commenters stated the presence (or absence) of laterality is not a factor in the nine guiding principles for establishing the severity level of an ICD–10 code. Therefore, these commenters suggested that CMS withdraw its possible adoption of a change, as the agency's own principles for establishing the severity level of an ICD–10 code do not support this change.

Response: In prior rulemaking, our clinical advisors reviewed the resource use impact reports and suggested modifications to the initial CC subclass assignments when clinically appropriate based on review of the mathematical data as well as consideration of the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses. As discussed in the proposed rule and noted earlier in this section, we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles. We believe the possible adoption of a change to the severity level designation of diagnosis codes when there are more specific codes available in that code subcategory that recognize laterality will have the downstream effect of strengthening the data used in such analysis. In regards to the comment that laterality in not listed as a factor in the nine guiding principles, our clinical advisors state that determining laterality is inherent to the guiding principle that states ''typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).'' If a higher level of care is required to address the diagnosis as a secondary diagnosis, then the laterality affected in most instances should be able to be determined in the course of the associated intensive monitoring, greater number of caregivers, and/or additional testing in most instances. We also note that if a procedure is performed to address a diagnosis as a secondary diagnosis, the laterality must be known and documented in order to assign an ICD–10–PCS code because ICD–10–PCS requires the use of laterality since ''unspecified'' is not an anatomical option in the procedure classification.

Comment: A commenter requested that CMS provide transparency in reference to the table that displays the distribution of volume within these codes for a better representation of the impact. The commenter noted that the table indicates that only 4% of the neoplasm codes would be impacted under the proposal; however, when reviewing the distribution of cases, the commenter stated that it appears that neoplasms were actually heavily impacted with the highest volume of cases.

Response: We note that the table displayed in the proposed rule compares the Version 38.1 ICD–10 MS–DRG severity level list and the potential Version 39 ICD–10 MS–DRG severity level list by each of the 22 chapters of the ICD–10–CM classification to display how each chapter of ICD–10–CM might be affected by these modifications. This table was not intended to represent an analysis of the claims reporting the 3,490 codes as listed.

Comment: A few commenters suggested that CMS analyze the frequency of use of unspecified codes, their impact on resource utilization, and also the typical documentation practices for acute stays with these conditions which may or may not include specificity before changing the severity designation of these codes. These commenters recommended that CMS conduct an analysis of how often the unspecified codes in question are actually used; how much resources they consume; and the standard documentation for the patient stays associated with the use of these codes.

Response: Table 6P.2a associated with the proposed rule contained data describing the impact on resource use when reported as a secondary diagnosis for all 3,490 ICD–10–CM unspecified diagnosis codes, generated using discharge claims from the September 2019 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, including the number of cases reporting these unspecified codes We note that we have made complete impact on resource use files available so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2018 MedPAR file, FY 2019 MedPAR file and the FY 2020 MedPAR file. The link to these files is posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

In response to the comment that CMS review the typical documentation practices for acute stays with these conditions, we note that medical professionals' documentation is already open to scrutiny by many, including employers, Federal and State reviewers, and auditors. We encourage providers to continue to focus efforts on improving their respective facilities medical record documentation practices.

Comment: Some commenters disagreed with the possible adoption of a change to the severity level designation of individual diagnosis codes listed in Table 6P. 2a associated with the proposed rule.

Many commenters opposed the inclusion of diagnosis codes that describe neoplasms in the list of codes. Commenters stated cancer patients typically are more complex than other types of patients, and often their cancer leads to greater resource utilization even when coded with an unspecified code. These commenters noted that while the neoplasm may still be under active

treatment, the specific side of the neoplasm may not be documented if the patient is admitted for a different, unrelated condition such as trauma or infections. Also, there are instances where patients with a known primary cancer are often evaluated, tested, and treated for a clinically likely yet unspecified secondary cancer site. These commenters stated in these cases, the lack of specificity is warranted, and the clinical presentation is still aligned with a CC or MCC. A commenter specifically identified code C56.9, Malignant neoplasm of unspecified ovary, and stated this code should remain a CC because some patients have extensive intraperitoneal metastases typical of (presumed) ovarian primary, and have pelvic involvement so extensive that resection is unable to be performed, and laterality is unable to be determined.

Response: Our clinical advisors reviewed this condition described by code C56.9 and agree with the commenters that this and other unspecified diagnosis codes that describe neoplasms should not be included in the list of unspecified diagnosis codes for consideration for a possible adoption of a change to the severity level designation. They agree that in certain presentations, the laterality affected might be difficult to determine in certain instances. Our clinical advisors believe the severity level designations for this subset of codes would be better addressed as part of our comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles.

Comment: A commenter identified diagnosis codes S02.113A, S02.113B, and S02.113K that describe unspecified occipital condyle fractures listed in Table 6P.2a associated with the proposed rule. The commenter noted that the ICD–10–CM classification does not have diagnosis codes that specify laterality when the type of occipital fracture (for example, Type 1, Type II, Type III) is unknown or unobtainable. Because unspecified codes must be assigned when the type of fracture is unknown, even when laterality is documented, the commenter suggested that these codes should be removed from the list of codes under consideration and retain their CC and MCC designations.

Response: We agree with the commenter that in subcategory S02.11 of the ICD–10–CM classification, there are no codes available that further specify laterality in the code description when the type of occipital condyle fracture is unknown. We further examined the list of diagnosis codes listed in Table 6P.2a, and noted diagnosis codes S02.119A, S02.119B and S02.119K that describe unspecified fractures of the occiput. Our clinical advisors noted that there are also no codes available in that classification that further specify laterality in the code description when the type of occipital fracture is unknown. Accordingly, our clinical advisors believe that these codes should not be included in the list of unspecified diagnosis codes for consideration for a possible adoption of a change to the severity level designation.

Comment: A commenter noted that ICD–10–CM diagnosis codes S82.001N and S82.001R that describe a fracture of the right patella were included in the list of codes in Table 6P.2a. The commenter stated these codes should be removed from Table 6P.2a because the laterality of ''right'' is specified within the code description.

Response: We appreciate the commenter noting that two diagnosis codes describing fractures affecting the right patella were included in Table 6P.2a associated with the proposed rule. We note that this was an inadvertent error. We further examined the list of diagnosis codes in Table 6P.2a, and noted diagnosis codes S78.911A and S78.921A that describe complete and partial traumatic amputation of right hip and thigh, respectively, were also inadvertently included in the list of ''unspecified'' diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site.

Comment: A commenter stated they disagreed with removing the severity designation of an unspecified code that is internal to the body and cannot be visualized externally. This would include all of the codes involving conditions of internal organs, vessels or body parts (for example, neoplasm, DVT, etc.).

Response: In response to this comment, we further examined the list of diagnosis codes in Table 6P.2a, and note the following:

- Our clinical advisors noted that codes S02.118A, S02.118B, and S02.118Kwhich describe other fractures of occiput, S04.819A which describes an injury of olfactory [1st] nerve, and S04.9XXA which describes an injury of unspecified cranial nerve were listed in Table 6P.2a. Our clinical advisors stated that in cases of traumatic injury, laterality may not be easily identified in occipital fractures or injuries to olfactory or cranial nerves.
- Our clinical advisors noted codes S32.9XXA, S32.9XXB, and S32.9XXK that describe fractures of unspecified parts of lumbosacral spine and pelvis; codes S36.209A, S36.249A, S36.259A, and S36.269A that describe injury and laceration to unspecified parts of the pancreas; code S36.509A that describes an unspecified injury of an unspecified part of colon; code S36.90XA that describes an unspecified injury of an unspecified intra-abdominal organ; code S37.90XA that describes an unspecified injury of unspecified urinary and pelvic organ; code T27.3XXA that describes a burn of an unspecified part of the respiratory tract; and T27.7XXA that describes a corrosion of an unspecified part of the respiratory tract were listed in Table 6P.2a. Our clinical advisors note that while we encourage the reporting and coding to the highest possible level of specificity based on documentation, the codes listed in Table 6P.2a were intended to be limited to ''unspecified'' diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site involved, when the location could be on the right, the left, or could be bilateral; and not parts of body sites.

Therefore, after further consideration, and for the reasons noted, we believe that the 58 ICD–10–CM diagnosis codes listed in the following table should not be included for consideration of changing the severity level designation as part of the list of ''unspecified'' diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site.

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ICD-10-CM Code	Code Description
C34.00	Malignant neoplasm of unspecified main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C46.50	Kaposi's sarcoma of unspecified lung
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C56.9	Malignant neoplasm of unspecified ovary
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.9	Malignant neoplasm of unspecified ureter
C72.20	Malignant neoplasm of unspecified olfactory nerve
C72.30	Malignant neoplasm of unspecified optic nerve
C72.40	Malignant neoplasm of unspecified acoustic nerve
C72.50	Malignant neoplasm of unspecified cranial nerve
C74.00	Malignant neoplasm of cortex of unspecified adrenal gland
C74.10	Malignant neoplasm of medulla of unspecified adrenal gland
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland
C78.00	Secondary malignant neoplasm of unspecified lung
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.60	Secondary malignant neoplasm of unspecified ovary
C79.70	Secondary malignant neoplasm of unspecified adrenal gland

S02.113A	Unspecified occipital condyle fracture, initial encounter for closed fracture
S02.113B	Unspecified occipital condyle fracture, initial encounter for open fracture
S02.113K	Unspecified occipital condyle fracture, subsequent encounter for fracture with nonunion
S02.118A	Other fracture of occiput, unspecified side, initial encounter for closed fracture
S02.118B	Other fracture of occiput, unspecified side, initial encounter for open fracture
S02.118K	Other fracture of occiput, unspecified side, subsequent encounter for fracture with nonunion
S02.119A	Unspecified fracture of occiput, initial encounter for closed fracture
S02.119B	Unspecified fracture of occiput, initial encounter for open fracture
S02.119K	Unspecified fracture of occiput, subsequent encounter for fracture with nonunion
S04.819A	Injury of olfactory [1st] nerve, unspecified side, initial encounter
S04.9XXA	Injury of unspecified cranial nerve, initial encounter
S32.9XXA	Fracture of unspecified parts of lumbosacral spine and pelvis, initial encounter for closed fracture
S32.9XXB	Fracture of unspecified parts of lumbosacral spine and pelvis, initial encounter for open fracture
S32.9XXK	Fracture of unspecified parts of lumbosacral spine and pelvis, subsequent encounter for fracture with nonunion
S36.209A	Unspecified injury of unspecified part of pancreas, initial encounter
S36.249A	Minor laceration of unspecified part of pancreas, initial encounter
S36.259A	Moderate laceration of unspecified part of pancreas, initial encounter
S36.269A	Major laceration of unspecified part of pancreas, initial encounter
S36.509A	Unspecified injury of unspecified part of colon, initial encounter
S36.90XA	Unspecified injury of unspecified intra-abdominal organ, initial encounter
S37.90XA	Unspecified injury of unspecified urinary and pelvic organ, initial encounter
S78.911A	Complete traumatic amputation of right hip and thigh, level unspecified, initial encounter
S78.921A	Partial traumatic amputation of right hip and thigh, level unspecified, initial encounter
S82.001N	Unspecified fracture of right patella, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion
S82.001R	Unspecified fracture of right patella, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with malunion
T27.3XXA	Burn of respiratory tract, part unspecified, initial encounter
T27.7XXA	Corrosion of respiratory tract, part unspecified, initial encounter

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Comment: Some commenters suggested that CMS can meet its goal to improve coding specificity through other mechanisms, such as working with the Cooperating Parties for ICD–10 to update coding guidelines to allow coding specificity from other clinical staff documentation. These commenters indicated they are supportive of CMS' efforts but believe CMS should first focus on provider outreach and education and consider updating the ICD–10–CM Official Guidelines for Coding and Reporting. Commenters

noted the ICD–10–CM Official Guidelines require that these codes be based only on provider documentation for the current encounter and prohibits coders from using previous encounters or problem lists to obtain the required specificity. These commenters stated if the coding guidelines from the Cooperating Parties were updated in advance of any severity level designation changes being finalized, the use of unspecified codes would likely diminish. Another commenter stated that unless the ICD–10–CM guidelines are liberalized so that code assignment can be obtained from other documents other than provider documentation for that encounter, the possible adoption of a change to the severity level designation will create undue burden. Another commenter noted without an update to the coding guidelines, hospitals will need to expand their clinical documentation improvement programs to prompt physicians to change their documentation practices on each applicable hospital encounter.

Response: The ICD–10–CM Official Guidelines for Coding and Reporting have been revised effective October 1, 2021 to provide additional guidance as it relates to the source documentation for code assignment. We believe this update will alleviate the concerns expressed by these commenters. Specifically, Section I.B.13 of the guidelines have been updated to state ''when laterality is not documented by the patient's provider, code assignment for the affected side may be based on medical record documentation from other clinicians. If there is conflicting medical record documentation regarding the affected side, the patient's attending provider should be queried for clarification. Codes for ''unspecified'' side should rarely be used, such as when the documentation in the record is insufficient to determine the affected side and it is not possible to obtain clarification. In this context, ''clinicians'' other than the patient's provider refer to healthcare professionals permitted, based on regulatory or accreditation requirements or internal hospital policies, to document in a patient's official medical record.'' Corresponding revisions to the guidelines can also be found in section I.B.14. Therefore, we believe that the updates made to the coding guidelines address that aspect of the commenters' concerns.

We encourage the commenters to review the Official ICD–10–CM Coding Guidelines, which can be found on the CDC website at: *http://www.cdc.gov/nchs/icd/icd10.htm.*

Comment: A number of commenters recommended (or urged) CMS to delay any possible change to the designation of these codes for at least two years to give hospitals and their physicians time to prepare. These commenters stated a change of this magnitude should not be implemented without giving providers time to restructure physician documentation improvement plans and to provide additional education to physicians and coders related to documentation practices. These commenters also stated a delay will give hospitals the time needed to update computer-assisted coding systems to incorporate this change to reduce the administrative burden on physicians related to documentation. Other commenters stated more time is needed before finalizing any policy decisions since this change impacts the quality and risk of mortality scores generated by commercial insurers who often follow CMS' coding and MS–DRG changes. Another commenter stated that this is a significant change from an operational perspective that, if implemented, will create significant administrative burden for hospitals at a time when administrative and clinical resources are still stretched thin by the COVID–19 PHE.

Response: We appreciate the commenter's concern's after consideration of the public comments we received, we are maintaining the severity level designation of all ''unspecified'' diagnosis codes currently designated as a CC or MCC where there are other codes available in that code subcategory that further specify the anatomic site for FY 2022. Instead, we are finalizing the Unspecified code MCE edit option as discussed in the proposed rule, which we believe provides additional time to educate providers while not affecting the payment the provider is eligible to receive. We refer the reader to section II.D.14.e. of the preamble of this final rule, for the complete discussion.

While we remain committed to fostering the documentation and reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition, we believe additional time is needed before adopting a change to the severity level designation of all ''unspecified'' diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site. This time will allow the industry an opportunity to educate coders on the updated guidelines and to offer assistance on proper documentation to providers.

We continue to be interested in receiving feedback on how we might otherwise foster the documentation and reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data. Comments should be directed to the MS–DRG Classification Change Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov*.

d. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2022

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25180) we noted the following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2022 and are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Table 6I.1—Proposed Additions to the MCC List—FY 2022;
Table 6I.2—Proposed Deletions to the MCC List—FY 2022; and
Table 6J.1—Proposed Additions to the CC List—FY 2022.

Comment: Commenters agreed with the proposed additions and deletions to the MCC and CC lists as shown in tables 6I.1, 6I.2, and 6J.1 associated with the proposed rule.

Response: We appreciate the commenters' support.

The following tables associated with this final rule reflect the finalized severity levels under Version 39 of the ICD–10 MS–DRGs for FY 2022 and are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Table 6I. —Complete MCC List—FY 2022;
Table 6I.1—Additions to the MCC List—FY 2022;
Table 6I.2—Deletions to the MCC List—FY 2022;
Table 6J. —Complete CC List—FY 2022;
Table 6J.1—Additions to the CC List—FY 2022; and
Table 6J.2—Deletions to the CC List—FY 2022.

We note that in the FY 2022 IPPS/LTCH PPS proposed rule there was not

a Table 6J.2—Proposed Deletions to the CC List—FY 2022 listed because we were not specifically proposing to delete any diagnosis codes from the current CC list effective with discharges on October 1, 2021 for FY 2022. However, we have included Table 6J.2 in association with this final rule for completeness, to display diagnosis code M35.8 (Other specified systemic involvement of connective tissue) that was previously designated as a CC in FY 2020 and was deleted effective January 1, 2021 due to the creation of diagnosis codes, M35.81 (Multisystem inflammatory syndrome) and M35.89 (Other specified systemic involvement of connective tissue) effective January 1, 2021 as displayed in the footnote of Table 6A.—New Diagnosis Codes —FY 2022. Similar to the process we described in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32559), where we solicited comments and provided the public an opportunity to comment on the severity level designations (in addition to the MDC and MS–DRG assignments) that had been implemented for the two diagnosis codes (U07.0 and U07.1) effective with discharges on and after April 1, 2020 (FY 2020) for FY 2021 consideration, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25191 through 25192), we provided the list of six diagnosis codes that were effective with discharges on and after January 1, 2021in Table 6A.—New Diagnosis Codes—FY 2022 associated with the proposed rule and likewise, provided the public an opportunity to comment on the severity level designations (in addition to the MDC and MS–DRG assignments) that had been implemented for those six diagnosis codes, for FY 2022 consideration. We did not receive any comments suggesting changes to the severity level (or MDC and MS–DRG assignments) for diagnosis codes M35.81 or M35.89 that were implemented on January 1, 2021, therefore, as shown in Table 6A.-New Diagnosis Codes-FY 2022 associated with this final rule, we are maintaining the CC severity level for these two diagnosis codes and displaying in Table 6J.2—Deletions to the CC List—FY 2022 also associated with this final rule, the corresponding deletion of diagnosis code M35.8 from the CC list that was implemented January 1, 2021 for completeness.

e. CC Exclusions List for FY 2022

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 38.1 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180) we discussed our request for public comments on potential changes to the severity level for 3,490 diagnosis codes describing an ''unspecified'' anatomic site, from a CC severity level to a NonCC severity level, for FY 2022. We referred the reader to Table 6P.3a associated with the proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for the list of the 3,490 diagnosis codes that are currently listed in Part 1 of the CC Exclusions List and are defined as a CC when reported as a secondary diagnosis. Table 6P.3a is divided into several tabs, with the first tab titled ''SDX Codes and Exclu Categories'' containing columns A, B, and C. Column A (titled ''ICD–10–CM Code'') lists the ''unspecified'' diagnosis codes that are currently listed in Part 1 of Appendix C of the CC Exclusions List, column B (titled ''Description'') lists the narrative description of each diagnosis code, and column C (titled Exclusion Category) contains a hyperlink to the collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC diagnosis to be considered as a NonCC. For example, for line 2, Column A displays diagnosis code C34.00, column B displays ''Malignant neoplasm of unspecified main bronchus'' and column C displays a hyperlink to Exclusion Category number 280. When the user clicks on the hyperlink for number 280, they are directed to another tab labeled ''PDX Category 280'' that contains the list of diagnosis codes which, when reported as the principal diagnosis, would cause the corresponding CC diagnosis to be considered as a NonCC. In connection with the request for public comments on the potential changes to the severity level for 3,490 diagnosis codes describing an ''unspecified'' anatomic site, from a CC severity level to a NonCC severity level for FY 2022, Table 6P.3a was made available for readers to review and consider the list of the 3,490 ''unspecified'' diagnosis codes that are currently included in Part 1 of the CC Exclusions List and the principal diagnosis exclusion category with which they are currently associated. In the proposed rule we stated that if we were to finalize the potential changes to the severity level for the 3,490 diagnosis codes describing an ''unspecified'' anatomic site from a CC severity level to

a NonCC severity level for FY 2022, we would also finalize the removal of these codes from the CC Exclusions List for FY 2022. As discussed previously, we are not finalizing the changes to the severity level for the 3,490 diagnosis codes describing an ''unspecified'' anatomic site from a CC severity level to a NonCC severity level for FY 2022, and therefore we are also not finalizing the removal of these codes from the CC Exclusions List for FY 2022.

In the proposed rule we discussed three requests we received related to the CC Exclusions List logic.

We received a request to review the secondary diagnoses that are excluded as a CC or MCC in the CC Exclusions List logic when any one of the following three diagnosis codes is reported as the principal diagnosis.

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ICD-10-CM Code	Code Description
O99.891	Other specified diseases and conditions complicating pregnancy
O99.892	Other specified diseases and conditions complicating childbirth
O99.893	Other specified diseases and conditions complicating puerperium

According to the requestor, in the ICD–10 MS–DRGs version 37.2 CC Exclusions List logic, the predecessor code for the listed diagnosis codes, diagnosis code O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium) is listed in the collection of principal diagnosis list number 1000, therefore, when a CC or MCC secondary diagnosis associated with that principal diagnosis list describes a condition as occurring in pregnancy, childbirth or the puerperium, the CC Exclusions List logic will render that diagnosis code as a NonCC. The requestor stated that because diagnosis code O99.89 under version 37.2 of the ICD–10 MS–DRGs is now a subcategory under version 38.1 of the ICD–10 MS–DRGs, with three unique diagnosis codes to specify which obstetric stage the patient is in, that further analysis of the new diagnosis codes (O99.891, O99.892, and O99.893) should occur to determine if changes to the collection of principal diagnosis list is warranted. The requestor provided three examples for CMS to review and consider for possible changes to the CC Exclusions List logic.

In the first example, the requestor noted that diagnosis code O72.1 (Other immediate postpartum hemorrhage) is listed as a CC secondary diagnosis associated with the collection of principal diagnosis list number 1000, and that under the ICD–10 MS–DRGs version 38.1 CC Exclusions List logic, the diagnosis listed in principal diagnosis collection 1000 is now diagnosis code O99.893 (Other specified diseases and conditions complicating puerperium). Thus, both diagnosis codes (O72.1 and O99.893) are describing conditions occurring specifically in the postpartum or puerperium period. The postpartum period is defined as the period beginning immediately after delivery and continues for six weeks following delivery. A postpartum complication is any complication occurring within the six-week period. The requestor stated that because diagnosis code O72.1 is assigned for documented postpartum uterine atony with hemorrhage when it occurs immediately following the delivery of the baby and placenta, that CMS should review diagnosis code O99.892 (Other specified diseases and conditions complicating childbirth) and determine if it should be added to the collection of principal diagnosis list number 1000 to cause diagnosis code O72.1 to be considered as a NonCC when diagnosis code O99.892 is reported as the principal diagnosis.

In the second example, the requestor noted that diagnosis code O98.32 (Other infections with a predominantly sexual mode of transmission complicating childbirth) is associated with principal diagnosis collection number 1012. The requestor also noted that principal diagnosis collection number 1012 does not list diagnosis codes O99.891, O99.892, or O99.893 as a principal diagnosis to exclude the CC secondary diagnosis code O98.32, however, it does list diagnosis codes O98.311 (Other infections with a predominantly sexual mode of transmission complicating pregnancy, first trimester), O98.312 (Other infections with a predominantly sexual mode of transmission complicating pregnancy, second trimester), and O98.313 (Other infections with a predominantly sexual mode of transmission complicating pregnancy, third trimester) as a principal diagnosis to exclude the CC secondary diagnosis code O98.32. The requestor recommended CMS review diagnosis codes O98.32 (Other infections with a predominantly sexual mode of transmission complicating childbirth) and O98.33 (Other infections with a predominantly sexual mode of transmission complicating the puerperium), to determine if diagnosis codes O99.891, O99.892 or O99.893, when reported as a principal diagnosis, should exclude CC secondary diagnosis codes O98.32 and O98.33. Thus, the requestor suggested CMS consider if it is appropriate to add diagnosis codes O99.891, O99.892 and O99.893 to principal diagnosis collection number 1012 to cause diagnosis code O98.32 to be considered as a NonCC when diagnosis codes O99.891, O99.892 or O99.893 are reported as the principal diagnosis.

In the third example, the requestor noted that diagnosis code O87.2 (Hemorrhoids in the puerperium) is associated with principal diagnosis collection number 4041. The requestor also noted that principal diagnosis collection number 4041 lists diagnosis code O99.893 as a principal diagnosis to exclude the CC diagnosis code O87.2, however, it does not list diagnosis code O99.892. The requestor further noted that the ''Includes'' note at Category O87 (Venous complications and hemorrhoids in the puerperium) in the FY 2021 ICD–10–CM Tabular List includes ''venous complications in labor, delivery and the puerperium'', therefore, diagnosis code O87.2 would also be reported for documented hemorrhoids during labor and delivery. The requestor recommended CMS review diagnosis code O99.892 to determine if, when reported as a principal diagnosis, it should exclude CC diagnosis code O87.2. Thus, the requestor suggested CMS consider if it is appropriate to add diagnosis code O99.892 to principal diagnosis collection number 4041 to cause diagnosis code O87.2 to be considered as a NonCC when diagnosis code O99.892 is reported as the principal diagnosis.

We stated in the proposed rule that we reviewed diagnosis codes O99.891, O99.892 and O99.893 with respect to the principal diagnosis collection list

and because these diagnosis codes are specifically describing ''other specified diseases and conditions complicating pregnancy, childbirth, and the puerperium,'' respectively, we do not believe that any of these three diagnosis codes, when reported as a principal diagnosis, should exclude any CC secondary diagnosis. In cases where any one of these three diagnosis codes is reported as a principal diagnosis, which are generally anticipated to be rare, it is understood that there is not a more specific diagnosis code available in the classification to report as the principal diagnosis that identifies the underlying or associated cause of the disease or the condition complicating the specific obstetric stage (pregnancy, childbirth, or puerperium), hence the ''other specified'' in the code title. Specifically, the title of category O99 is ''Other maternal diseases classifiable elsewhere but complicating pregnancy, childbirth and the puerperium'' and there are nine subcategories, each of which is generally associated with a single organ system or etiology, with the exception of the ''other specified'' subcategory (O99.8) as displayed in the following table.

Subcategories within ICD-10-CM Category O99 Other Maternal Diseases Classifiable Elsewhere But Complicating Pregnancy, Childbirth and the Puerperium

Subcategory	Description
O99.0	Anemia complicating pregnancy, childbirth, and the puerperium
O99.1	Other diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism complicating pregnancy, childbirth and the puerperium
O99.2	Endocrine, nutritional and metabolic diseases complicating pregnancy, childbirth and the puerperium
O99.3	Mental disorders in diseases of the nervous system complicating pregnancy, childbirth and the puerperium
O99.4	Diseases of the circulatory system complicating pregnancy, childbirth and the puerperium
O99.5	Diseases of the respiratory system complicating pregnancy, childbirth and the puerperium
O99.6	Diseases of the digestive system complicating pregnancy, childbirth and the puerperium
O99.7	Diseases of the skin and subcutaneous tissue complicating pregnancy, childbirth and the puerperium
O99.8	Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium

The instructional note at category O99 states ''use additional code to identify specific condition'' and included at each subcategory (O99.0–O99.7) are a range of codes that refer to diagnoses that are associated with the condition in the title of the subcategory that are to be reported in addition to the applicable code within the respective subcategory. For example, at subcategory O99.0 (Anemia complicating pregnancy, childbirth, and the puerperium), the range of associated codes to identify the specific condition (for example, type of anemia) includes conditions in diagnosis code range D50–D64, meaning that when any one of the diagnosis codes under subcategory O99.0 describing anemia complicating a specific obstetric stage (pregnancy, childbirth, or puerperium) is reported, a code within the D50–D64 code range to identify the specific type of anemia would also be expected to be reported when supported by the medical record documentation. It is therefore reasonable to associate the two conditions (one from subcategory O99.0 and one from code range D50–D64) when reported on a claim. However, the same cannot be stated for subcategory O99.8. There is no range of associated codes from which users are instructed to report located at this particular subcategory in addition to the specific code under sub-subcategory O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium). We note that subcategory O99.8 and sub-subcategory O99.89 have the same title. Therefore, when a diagnosis code from other than that sub-subcategory is reported that describes a condition occurring in any one of the obstetric stages (pregnancy, childbirth, or puerperium) it is not clear if the condition can reasonably be associated to correspond to the ''other specified diseases and conditions'' diagnosis. In addition, the code ranges included at subcategory O99.8 are D00–D48, H00–H95, M00–N99, and Q00–Q99. Consequently, diagnosis codes within those code ranges would be expected to be reported with one of the diagnosis codes under subcategory O99.8 when reported as a principal diagnosis.

In all three of the requestor's examples, the diagnosis codes provided for CMS to review and consider are located in the ''O'' code range (O72.1, O98.32, and O87.2 in addition to O99.891, O99.892, and O99.893). As noted previously, the code ranges included at subcategory O99.8 as listed, do not include any codes in the ''O'' code range. Upon review of the diagnosis codes provided by the requestor, it is also reasonable to expect that any one of those diagnosis codes (O72.1, O98.32, and O87.2) could be

reported as a principal diagnosis alone. For instance, there are no instructional notes at diagnosis code O72.1 that preclude that diagnosis code from being reported as the principal diagnosis.

We stated in the proposed rule that during our review of the CC Exclusions List logic in response to the requestor's recommendations, we also identified some diagnosis codes describing the specific trimester of pregnancy that we believe warrant further examination. We noted that we were unable to fully evaluate these conditions for FY 2022, therefore, we will continue to analyze for future rulemaking.

For the reasons discussed, we stated in the proposed rule that we do not believe that any of the three diagnosis codes (O99.891, O99.892, and O99.893), when reported as a principal diagnosis, should exclude any CC secondary diagnosis. Therefore, we proposed to remove diagnosis codes O99.891, O99.892, and O99.893 from the CC Exclusions List logic principal diagnosis collection lists. Specifically, we proposed to remove those diagnosis codes from the following principal diagnosis collection list numbers 0085, 0954, 0956 through 0963, 0972, 0988, 0991 through 0998, 1000 through 1002, 1004, 1006, 1009, 1011, 1014, 1015, 1019, 3999, 4000, 4002 through 4006, 4008, 4010, through 4013, 4017, 4020, 4021, 4023 through 4026, 4030, 4031, 4033 through 4043, 4050 through 4054, 4059 through 4063, 4065 and 4067, effective FY 2022.

We did not receive any comments opposing our proposal, therefore, we are finalizing the removal of diagnosis codes O99.891, O99.892, and O99.893 from the CC Exclusions List logic principal diagnosis collection lists identified for FY 2022.

In the proposed rule we also discussed a request we received to review diagnosis codes describing oxygen dependence, chronic obstructive pulmonary disease with exacerbation, and chronic respiratory failure with regard to assignment in MS–DRG 191 (Chronic Obstructive Pulmonary Disease with CC) and to consider whether any changes to principal diagnosis collection number 0744 in the CC Exclusions List logic are warranted.

The requestor provided diagnosis codes J44.1 (Chronic obstructive pulmonary disease with (acute) exacerbation), J96.11 (Chronic respiratory failure with hypoxia (CC)) and Z99.81 (Dependence on supplemental oxygen) for CMS to review. Specifically, the requestor suggested that if oxygen dependence, by definition, is clinically inherent to chronic respiratory failure, then CMS should consider adding diagnosis code J44.1 to the CC Exclusions List logic principal diagnosis collection list number 0744 and cause diagnosis code J96.11 to be considered as a NonCC when J44.1 is reported as the principal diagnosis.

We stated in the proposed rule that we reviewed the diagnosis codes and MS–DRG assignment as the requestor suggested. We confirmed that when diagnosis code J44.1 is reported as the principal diagnosis with the CC secondary diagnosis code J96.11, and secondary diagnosis code Z99.81, the resulting MS–DRG assignment is MS–DRG 191. We stated our belief that diagnosis code J96.11 should continue to group as a CC, to the ''with CC'' MS–DRG 191, when reported as a secondary diagnosis code with diagnosis code J44.1 reported as the principal diagnosis. We disagreed with the requestor's suggestion that every oxygen-dependent COPD patient has chronic respiratory failure, and that separately reporting the chronic respiratory failure is clinically redundant. Patients can be oxygen-dependent with COPD and not have a diagnosis of chronic respiratory failure. Therefore, we proposed to maintain the structure of principal diagnosis collection list number 0744 in the CC Exclusions List logic for FY 2022.

We did not receive any comments opposing our proposal, therefore, we are finalizing the proposal to maintain the structure of principal diagnosis collection list number 0744 in the CC Exclusions List logic for FY 2022.

Lastly, in the proposed rule we discussed a request we received to reconsider the MCC exclusions for diagnosis code I11.0 (Hypertensive heart disease with heart failure) when reported as the principal diagnosis. According to the requestor, there appears to be an inconsistency for the CC Exclusions List logic. Specifically, the requestor noted that when diagnosis code I11.0 is reported as the principal diagnosis, it causes the following MCC secondary diagnosis codes to be considered as a NonCC.

ICD-10-CM Code	Code Description
I50.23	Acute on chronic systolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure

However, the requestor stated that diagnosis codes I50.21 (Acute systolic (congestive) heart failure) and I50.31 (Acute diastolic (congestive) heart failure) are not excluded from acting as MCCs when diagnosis code I11.0 is reported as the principal diagnosis. The requestor also stated that all diagnosis codes in category I50 (Heart Failure) share common etiologies and demonstrate comparable severity of illness. Therefore, the requestor suggested that none of the conditions in this category (I50) should be excluded from acting as a MCC when diagnosis code I11.0 is reported as a principal diagnosis.

In the proposed rule we stated that we examined all the diagnosis codes in category I50 with regard to the CC Exclusions List logic. In addition to diagnosis code I11.0, we also reviewed diagnosis code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease) when reported as a principal diagnosis because that diagnosis code also has the Tabular instruction ''use additional code to identify the type of heart failure''.

We found additional inconsistencies in the CC secondary diagnosis heart failure codes where some diagnoses were excluded depending on the principal diagnosis reported and others were not excluded. As a result, we proposed to revise the CC Exclusions Logic list for diagnosis codes I11.0 and

I13.2 when reported as a principal diagnosis to ensure they are consistent in the CC and MCC diagnoses they exclude. In the proposed rule we showed the findings for each diagnosis code in category I50 in the following table with respect to the current severity level (MCC, CC or NonCC), if it is currently excluded as a CC or MCC when reported with either diagnosis code I11.0 or I13.2 as the principal diagnosis, and our proposal under the CC Exclusions List logic for FY 2022.

ICD-10-CM Code	Code Description	Principal Diagnosis I11.0	Principal Diagnosis I13.2	Proposal for FY 2022
I50.1 (CC)	Left ventricular failure, unspecified	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.20 (CC)	Unspecified systolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.21 (MCC)	Acute systolic (congestive) heart failure	Not excluded	Not excluded	No change
I50.22 (CC)	Chronic systolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.23 (MCC)	Acute on chronic systolic (congestive) heart failure	Excluded	Not excluded	Remove from CC Exclusion List for Principal Dx I11.0

I50.30 (CC)	Unspecified diastolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.31 (MCC)	Acute diastolic (congestive) heart failure	Not excluded	Not excluded	No change
I50.32 (CC)	Chronic diastolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.33 (MCC)	Acute on chronic diastolic (congestive) heart failure	Excluded	Not excluded	Remove from CC Exclusion List for Principal Dx I11.0
I50.40 (CC)	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.41 (MCC)	Acute combined systolic (congestive) and diastolic (congestive) heart failure	Excluded	Not excluded	Remove from CC Exclusion List for Principal Dx I11.0
I50.42 (CC)	Chronic combined systolic (congestive) and diastolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.43 (MCC)	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure	Excluded	Not excluded	Remove from CC Exclusion List for Principal Dx I11.0
I50.810 (NonCC)	Right heart failure, unspecified	Not excluded	Not excluded	No change
I50.811 (NonCC)	Acute right heart failure	Not excluded	Not excluded	No change
I50.812 (NonCC)	Chronic right heart failure	Not excluded	Not excluded	No change
I50.813 (NonCC)	Acute on chronic right heart failure	Not excluded	Not excluded	No change
I50.814 (NonCC)	Right heart failure due to left heart failure	Not excluded	Not excluded	No change
I50.82 (NonCC)	Biventricular heart failure	Not excluded	Not excluded	No change
I50.83 (NonCC)	High output heart failure	Not excluded	Not excluded	No change
I50.84 (NonCC)	End stage heart failure	Not excluded	Not excluded	No change
I50.89 (NonCC)	Other heart failure	Not excluded	Not excluded	No change
I50.9 (NonCC)	Heart failure, unspecified	Not excluded	Not excluded	No change

Comment: Several commenters agreed with our proposal to revise the CC Exclusions List logic for diagnosis codes I11.0 and I13.2 when either code is reported as a principal diagnosis. A commenter also suggested that the changes made for diagnosis code I13.2 should be made for diagnosis code I13.0 (Hypertensive heart and chronic kidney

disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease).

Response: With regard to the commenter's suggestion that changes made for diagnosis code I13.2 should also be made for diagnosis code I13.0, we appreciate the feedback. We were unable to fully evaluate the request for FY 2022 consideration, therefore, we will examine this issue for future rulemaking and determine if there are other diagnoses that should also be considered further.

After consideration of the comments received, we are finalizing our proposal to revise the CC Exclusions Logic list for diagnosis codes I11.0 and I13.2 when reported as a principal diagnosis, without modification, for FY 2022.

We also proposed additional changes to the ICD–10 MS–DRGs Version 39 CC Exclusion List based on the diagnosis and procedure code updates as discussed in section II.D.13. of the FY 2022 IPPS/LTCH PPS proposed rule and set forth in Tables 6G.1, 6G.2, 6H.1, and 6H.2 associated with the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Comment: A commenter stated they did not agree with the proposed MCC exclusion for new diagnosis codes S06.A0XA (Traumatic brain compression without herniation, initial encounter) and S06.A1XA (Traumatic brain compression with herniation, initial encounter) as shown in Tables 6G.1 and 6G.2 associated with the proposed rule, when reported with principal diagnoses from subcategories S06.1, S06.2, S06.3, S06.4, S06.5, or S06.6. According to the commenter, patients with brain compression secondary to traumatic intracranial injuries have significantly higher morbidity and mortality, longer length of stays, and greater consumption of resources than those without brain compression. The commenter identified that the current code for brain compression (G93.5) has been separately reportable as a MCC with principal diagnoses from subcategories S06.4, S06.5, and S06.6; and maintained that the new codes for brain compression should reasonably retain MCC severity. The commenter added that some epidural, subdural, and subarachnoid hemorrhages are small, easily monitored and without compression; but others result in significant brain compression with longer length of stays and greater consumption of resources with the MCC severity differentiating these groups of patients. The commenter asserted that brain compression should also be a MCC when reported with principal diagnoses from subcategories S06.2 (Diffuse traumatic brain injury) and S06.3 (Focal traumatic brain injury) for the same reasons.

Lastly, the commenter stated that because diffuse traumatic brain injury with diffuse cerebral edema must be reported with a single code from subcategory S06.1- per the Excludes 1 note at subcategory S06.2-, it is additionally reasonable for brain compression to be a MCC severity with a principal diagnosis of traumatic cerebral edema (S06.1-) in order to differentiate between patients with and without the life-threatening complication of brain compression.

Response: We appreciate the commenter's feedback. It is not clear from the commenter's statement if they were unable to differentiate the content between Table 6G.1 and Table 6G.2 associated with the proposed rule. We note that for Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a proposed CC exclusion is shown with an asterisk and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. We believe the commenter may have inadvertently reviewed Table 6G.2 as if it were Table 6G.1. To clarify, diagnosis codes S06.A0XA and S06.A1XA, as shown in Table 6G.1 with an asterisk, were proposed to be excluded from acting as a secondary diagnosis MCC when any one of the following diagnoses are reported as the principal diagnosis; G93.6 (Cerebral edema), G93.82 (Brain death), S06.1X0A (Traumatic cerebral edema without loss of consciousness, initial encounter), S06.A0XA (Traumatic brain compression without herniation, initial encounter), and S06.A1XA (Traumatic brain compression with herniation, initial encounter). We are providing the following table to illustrate how the contents of Table 6G.1 associated with the proposed rule (and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*), are displayed for these codes. We note that Table 6G.1 does not include the decimal point for any of the diagnosis codes listed.

*S06A0XA	*S06A1XA
G936	G936
G9382	G9382
S061X0A	S061X0A
S06A0XA	S06A0XA
S06A1XA	S06A1XA

BILLING CODE 4120–01–C

As shown in the table, codes S06.A0XA and S06.A1XA are the secondary diagnosis codes that were proposed for addition to the CC Exclusion List as shown with an asterisk, and the principal diagnoses proposed to exclude these codes from acting as a MCC are provided in the indented column immediately following each. Therefore, our proposal was not to exclude codes S06.A0XA and S06.A1XA from acting as a MCC when reported with principal diagnoses from subcategories S06.2, S06.3, S06.4, S06.5, or S06.6, as there are no codes from those subcategories listed in the table. With respect to subcategory S06.1, as shown in the table, diagnosis code S06.1X0A is listed as a principal diagnosis that would exclude codes S06.A0XA and S06.A1XA from acting as a MCC when reported as a secondary diagnosis, as proposed.

We acknowledge that diffuse traumatic brain injury with diffuse cerebral edema must be reported with a single code from subcategory S06.1- per the Excludes 1 note at subcategory S06.2-, therefore, we consulted with staff at the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the

lead responsibility for the ICD–10–CM diagnosis codes. The NCHS' staff confirmed that the Excludes 1 note at subcategory S06.2- requires further clinical review and consideration. We also examined the predecessor code for new diagnosis codes S06.A0XA and S06.A1XA, (code S06.1X0A), to identify the principal diagnosis collection list (list of principal diagnosis codes) that exclude code S06.1X0A from acting as a MCC and were the basis for the list of principal diagnosis codes proposed to exclude new diagnosis codes S06.A0XA and S06.A1XA from acting as a MCC when reported as a principal diagnosis. We note that code S06.1X0A is associated with principal diagnosis collection number 3977 and includes diagnosis codes G93.6, G93.82, and S06.1X0A, consistent with the principal diagnosis exclusions proposed for new diagnosis codes S06.A0XA and S06.A1XA.

We refer the reader to Table 6G.2 associated with the proposed rule (and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*), to review how codes S06.A0XA and S06.A1XA were displayed as principal diagnoses as shown with an asterisk, and the conditions proposed for addition to the CC Exclusion List to not count as a CC are provided in an indented column immediately following the affected principal diagnosis. Among the conditions proposed for addition to the CC Exclusion List to not count as a CC are those from subcategories S06.1, S06.2, S06.3, S06.4, S06.5, and S06.6. As such, we believe the commenter inadvertently reviewed Table 6G.2 as if it were Table 6G.1.

After consideration of the public comments received, and until such time the CDC/NCHS staff can review the Excludes note at subcategory S06.2- further, we are finalizing our proposal to exclude diagnosis codes S06.A0XA and S06.A1XA from acting as a MCC when one of the listed diagnosis codes from Table 6G.1 is reported as a principal diagnosis and we are also finalizing our proposal to exclude the listed diagnosis codes in Table 6G.2 from acting as a MCC when diagnosis code S06.A0XA or S06.A1XA is reported as the principal diagnosis.

As discussed in section II.D.13. of the preamble of this final rule, we are finalizing, without modification, the proposed assignments and designations for the diagnosis codes after consideration of the public comments received. Therefore, the finalized CC Exclusions List as displayed in Tables 6G.1, 6G.2, 6H.1, 6H.2, and 6K, associated with this final rule reflect the severity levels under V39 of the ICD–10 MS–DRGs.

We have developed Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2022; Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2022; Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2022; and Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2022; and Table 6K. Complete List of CC Exclusions-FY 2022.

For Table 6G.1, each secondary diagnosis code finalized for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses finalized to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions finalized for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code finalized for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the finalized deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Table 6K is a list of all of the codes that are defined as either CC or a MCC when used as a secondary diagnosis. Within the table each code is specifically indicated as CC or MCC. A table number is given to a collection of diagnosis codes which, when used as the principal diagnosis, will cause the CC or MCC to be considered as only a NonCC. Tables 6G.1., 6G.2., 6H.1., 6H.2, and 6K. associated with this final rule are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

The ICD–10 MS–DRGs Version 39 CC Exclusion List is included as Appendix C of the Definitions Manual (available in two formats; text and HTML). The manuals are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/MS-DRGClassifications-and-Software* and each format includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link (HTML version) is provided to a collection of diagnosis codes which, when used as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a non-CC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a non-CC.

13. Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised and deleted diagnosis and procedure codes, for FY 2022, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this final rule.

These tables are not published in the Addendum to the proposed rule or final rule, but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this final rule. As discussed in section II.D.16. of the preamble of this final rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25186) we proposed the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. We also stated that the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B. Consistent with our established process, we examined the MS–DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our proposed assignments and designations. Specifically, we reviewed the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we considered other factors that may be

relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We noted that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same MS–DRG or to have the same designation as the predecessor code.

Comment: A commenter stated they did not agree with the proposed severity level for diagnosis code I5A (Non-ischemic myocardial injury (non-traumatic)) shown as a CC in Table 6A.—New Diagnosis Codes. According to the commenter, the 4th Universal Definition of MI states that a non-ischemic myocardial injury is diagnosed only with an elevated troponin. The commenter recommended that the CC severity level for this diagnosis code be changed to a NonCC and to allow the underlying cause of the non-ischemic myocardial injury to act as the CC or MCC instead.

Response: We appreciate the commenter's feedback. Consistent with our annual process of assigning new diagnosis codes to MDCs, MS–DRGs, and designating a severity level (MCC, CC or NonCC), we reviewed the predecessor diagnosis code assignment for code I5A. The predecessor code for code I5A is diagnosis code I21.A9 (Other myocardial infarction type), which is designated as a MCC. Our clinical advisors did not agree with a MCC severity level assignment for code I5A because they stated nonischemic myocardial injury may be secondary to cardiac conditions such as myocarditis or non-cardiac conditions such as renal failure and the clinical evaluation and work up vary depending on the results of testing. Upon further review, they continue to believe that a CC severity level designation is warranted.

Comment: A commenter stated they did not agree with the proposed designation of procedure codes 07DT0ZX (Extraction of bone marrow, open approach, diagnostic) and 07DT0ZZ (Extraction of bone marrow, open approach) shown as Non-O.R. procedures in Table 6B.—New Procedure Codes. According to the commenter, these procedures should be classified as O.R. procedures because open incision down to bone with direct visualization of bone marrow during extraction requires operating room resources and anesthesia.

Response: We appreciate the commenter's feedback. Consistent with our annual process of assigning new procedure codes to MDCs, MS–DRGs, and classifying as an O.R. or Non-O.R. procedure, we reviewed the predecessor procedure code assignment for codes 07DT0ZX and 07DT0ZZ. The predecessor code for code 07DT0ZX is procedure code 079T0ZX (Drainage of bone marrow, open approach, diagnostic), which is designated as a Non-O.R. procedure and the predecessor code for code 07DT0ZZ is 079T0ZZ (Drainage of bone marrow, open approach) which is also designated as a Non-O.R. procedure. Our clinical advisors did not agree with an O.R. designation because they stated open bone marrow biopsy procedures would rarely be performed and rarely be the primary cause for an inpatient admission contributing to resource consumption. They indicated that if performed, it is more likely they would be conducted in connection with another open surgical procedure.

After consideration of the comments received, for FY 2022, we are maintaining the CC severity level for diagnosis code I5A and finalizing the Non-O.R. designation for procedure codes 07DT0ZX and 07DT0ZZ.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following tables associated with this final rule:

- Table 6A.—New Diagnosis Codes–FY 2022;
- Table 6B.—New Procedure Codes—FY 2022;
- Table 6C.—Invalid Diagnosis Codes—FY 2022;
- Table 6D.—Invalid Procedure Codes—FY 2022;
- Table 6E.—Revised Diagnosis Code Titles—FY 2022;
- Table 6F.—Revised Procedure Code Titles—FY 2022;
- Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2022;
- Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2022;
- Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List–FY 2022;
- Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2022;
- Table 6I.—Complete MCC List—FY 2022;
- Table 6I.1.—Additions to the MCC List—FY 2022;
- Table 6I.2.—Deletions to the MCC List—FY 2022;
- Table 6J.—Complete CC List—FY 2022;
- Table 6J.1.—Additions to the CC List—FY 2022;
- Table 6J.2.—Deletions to the CC List—FY 2022; and
- Table 6K.—Complete List of CC Exclusions—FY 2022

14. Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we made available the FY 2021 ICD–10 MCE Version 38 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 38 (and ICD–10 MS–DRGs) are posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

In the FY 2022 IPPS/LTCH PPS proposed rule, we addressed the MCE requests we received by the November 1, 2020 deadline. We also discussed the proposals we were making based on our internal review and analysis. In this FY 2022 IPPS/LTCH PPS final rule, we present a summation of the comments we received in response to the MCE requests and proposals presented based on internal review and analyses in the proposed rule, our responses to those comments, and our finalized policies.

In addition, as a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, we routinely make changes to the MCE. In the past, in both the IPPS proposed and final rules, we have only provided the list of changes to the MCE that were brought to our attention after the prior year's final rule. We historically have not listed the changes we have made to the MCE as a result of the new and modified codes approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting. These changes are approved too late in the rulemaking schedule for inclusion in the proposed rule. Furthermore, although our MCE policies have been described in our proposed and final

rules, we have not provided the detail of each new or modified diagnosis and procedure code edit in the final rule. However, we make available the finalized Definitions of Medicare Code Edits (MCE) file. Therefore, we are making available the FY 2022 ICD–10 MCE Version 39 Manual file, along with the link to the mainframe and computer software for the MCE Version 39 (and ICD–10 MS–DRGs), on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

a. External Causes of Morbidity Codes as Principal Diagnosis

In the MCE, the external cause codes (V, W, X, or Y codes) describe the circumstance causing an injury, not the nature of the injury, and therefore should not be used as a principal diagnosis.

As discussed in section II.D.13. of the preamble of the proposed rule and section II.D.13. of this final rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2021. We proposed to add the following new ICD–10–CM diagnosis codes to the External Causes of Morbidity edit code list.

BILLING CODE 4120–01–P

ICD-10-CM code	Code description
Y35.899A	Legal intervention involving other specified means, unspecified person injured, initial encounter
Y35.899D	Legal intervention involving other specified means, unspecified person injured, subsequent encounter
Y35.899S	Legal intervention involving other specified means, unspecified person injured, sequela

Comment: Commenters agreed with CMS' proposal to add the diagnosis codes listed in the previous table to the External Causes of Morbidity edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the External Causes of Morbidity edit code list under the ICD–10 MCE Version 39, effective October 1, 2021.

b. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 9–64 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

(1) Pediatric Diagnoses

Under the ICD–10 MCE, the Pediatric diagnoses category for the Age conflict edit considers the age range of 0 to 17 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.13. of the preamble of the proposed rule and section II.D.13. of this final rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2021. We proposed to add the following new ICD–10–CM diagnosis codes to the Pediatric diagnoses category code list under the Age conflict edit.

ICD-10-CM code	Code description
R63.31	Pediatric feeding disorder, acute
R63.32	Pediatric feeding disorder, chronic

Comment: Commenters agreed with CMS' proposal to add the diagnosis codes listed in the previous table to the Pediatric diagnoses category code list under the Age Conflict edit.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Pediatric diagnoses category code list under the Age Conflict edit in the ICD–10 MCE Version 39, effective October 1, 2021.

c. Sex Conflict Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for

example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

(1) Diagnoses for Females Only Edit

As discussed in section II.D.13. of the preamble of the proposed rule and section II.D.13. of this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2021. We proposed to add the following new ICD–10–CM diagnosis codes to the edit code list for the Diagnoses for Females Only edit.

ICD-10-CM code	Code description
C56.3	Malignant neoplasm of bilateral ovaries
C79.63	Secondary malignant neoplasm of bilateral ovaries

Comment: Commenters supported the proposal to add the ICD–10–CM diagnosis codes listed in the previous table to the Diagnoses for Females Only edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Diagnoses for Females Only edit code list under the ICD–10 MCE Version 39, effective October 1, 2021.

d. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

As discussed in section II.D.13. of the preamble of the proposed rule and section II.D.13. of this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2021. We stated in the proposed rule that as a result of proposed new instructional notes to ''Code first underlying disease'' (which indicate the proper sequencing order of the codes) for existing diagnosis codes found at subcategory M40.1 (Other secondary kyphosis) and subcategory M41.5 (Other secondary scoliosis) discussed at the September 8–9, 2020 ICD–10 Coordination and Maintenance Committee meeting, we were proposing to add the following new and, if those instructional notes were finalized, existing ICD–10–CM diagnosis codes at subcategories M40.1 and M41.5, to the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM code	Code description
G92.00	Immune effector cell-associated neurotoxicity syndrome, grade unspecified
G92.01	Immune effector cell-associated neurotoxicity syndrome, grade 1
G92.02	Immune effector cell-associated neurotoxicity syndrome, grade 2
G92.03	Immune effector cell-associated neurotoxicity syndrome, grade 3
G92.04	Immune effector cell-associated neurotoxicity syndrome, grade 4
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5
M40.10	Other secondary kyphosis, site unspecified
M40.12	Other secondary kyphosis, cervical region
M40.13	Other secondary kyphosis, cervicothoracic region
M40.14	Other secondary kyphosis, thoracic region
M40.15	Other secondary kyphosis, thoracolumbar region
M41.50	Other secondary scoliosis, site unspecified
M41.52	Other secondary scoliosis, cervical region
M41.53	Other secondary scoliosis, cervicothoracic region
M41.54	Other secondary scoliosis, thoracic region
M41.55	Other secondary scoliosis, thoracolumbar region
M41.56	Other secondary scoliosis, lumbar region
M41.57	Other secondary scoliosis, lumbosacral region
R0.54	Cough syncope
S06.A0XA	Traumatic brain compression without herniation, initial encounter
S06.A0XD	Traumatic brain compression without herniation, subsequent encounter
S06.A0XS	Traumatic brain compression without herniation, sequela
S06.A1XA	Traumatic brain compression with herniation, initial encounter
S06.A1XD	Traumatic brain compression with herniation, subsequent encounter
S06.A1XS	Traumatic brain compression with herniation, sequela
T40.715A	Adverse effect of cannabis, initial encounter
T40.715D	Adverse effect of cannabis, subsequent encounter
T40.715S	Adverse effect of cannabis, sequela
T40.716A	Underdosing of cannabis, initial encounter
T40.716D	Underdosing of cannabis, subsequent encounter
T40.716S	Underdosing of cannabis, sequela
T40.725A	Adverse effect of synthetic cannabinoids, initial encounter
T40.725D	Adverse effect of synthetic cannabinoids, subsequent encounter
T40.725S	Adverse effect of synthetic cannabinoids, sequela
T40.726A	Underdosing of synthetic cannabinoids, initial encounter
T40.726D	Underdosing of synthetic cannabinoids, subsequent encounter
T40.726S	Underdosing of synthetic cannabinoids, sequela
Z71.85	Encounter for immunization safety counseling

Z91.014	Allergy to mammalian meats
Z91.51	Personal history of suicidal behavior
Z91.52	Personal history of nonsuicidal self-harm
Z92.850	Personal history of Chimeric Antigen Receptor T-cell therapy
Z92.858	Personal history of other cellular therapy
Z92.859	Personal history of cellular therapy, unspecified
Z92.86	Personal history of gene therapy

Comment: Many commenters supported our proposal to add the diagnosis codes listed in the previous table to the Unacceptable Principal Diagnosis edit code list.

Response: We appreciate the commenters' support.

Comment: A commenter expressed disagreement with the proposal to add the listed diagnosis codes from subcategories M40.1 and M41.5 to the unacceptable principal diagnosis code edit list if the ''code first underlying disease'' notes are finalized. The commenter acknowledged that physicians can reasonably diagnose acquired, new onset scoliosis and/or kyphosis as ''secondary'' to an underlying condition; however, the commenter stated diagnostic workup must occur (usually as an outpatient) before the exact cause(s) can be determined, such as degenerative disc disease, spondylosis, osteoporosis, pathologic fracture, failed fusion, etc. According to the commenter, when there are two or more potential causes, physicians may be unable to identify one specific cause versus multifactorial causes and the commenter stated their concern that when queried for the underlying cause(s), the physician may respond that they are unable to determine. The commenter added that when secondary scoliosis and/or kyphosis are responsible for causing surgical hospitalizations, the ability to sequence these conditions as a principal diagnosis should remain when the underlying cause(s) cannot be obtained.

The commenter referenced language from the ICD–10–CM Official Guidelines for Coding and Reporting, with an emphasis on section I.A.13. Etiology/manifestation convention (''code first'', ''use additional code'' and ''in diseases classified elsewhere'' notes) which essentially states that ''Code first'' and ''Use additional code'' notes are also used as sequencing rules in the classification for certain codes that are not part of an etiology manifestation combination and section I.B.7. Multiple coding for a single condition, which states ''code first'' notes are also under certain codes that are not specifically manifestation codes but may be due to an underlying cause. When there is a ''code first'' note and an underlying condition is present, the underlying condition should be sequenced first, if known.

Response: We appreciate the commenters' feedback. We note that we consulted with the staff at the Centers for Disease Control and Prevention's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for the ICD–10–CM diagnosis codes. The NCHS' staff confirmed that the intent is that the listed diagnosis codes from subcategories M40.1 and M41.5 be reported as secondary diagnoses. The staff agreed that in cases where it could be more than one condition as the underlying cause (*E.g.* Multifactorial), that the guideline for the principal diagnosis could be applied. Section 11. C. (Two or more diagnoses that equally meet the definition for principal diagnosis.) in the ICD–10–CM Official Guidelines for Coding and Reporting.

After consideration of the public comments that we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Unacceptable Principal Diagnosis edit code list under the ICD–10 MCE Version 39, effective October 1, 2021.

In addition, as discussed in section II.D.13. of the preamble of the proposed rule and section II.D.13. of this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2021. Included in this table are the following ICD–10–CM diagnosis codes that are currently listed on the Unacceptable Principal Diagnosis edit code list. We proposed to delete these codes from the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM code	Code description
T40.7X5A	Adverse effect of cannabis (derivatives), initial encounter
T40.7X5D	Adverse effect of cannabis (derivatives), subsequent encounter
T40.7X5S	Adverse effect of cannabis (derivatives), sequela
T40.7X6A	Underdosing of cannabis (derivatives), initial encounter
T40.7X6D	Underdosing of cannabis (derivatives), subsequent encounter
T40.7X6S	Underdosing of cannabis (derivatives), sequela
Z91.5	Personal history of self-harm

Comment: Commenters agreed with our proposal to remove the codes listed in the previous table from the Unacceptable Principal Diagnosis edit code list since they are no longer valid effective October 1, 2021.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to remove the diagnosis codes previously listed from

the Unacceptable Principal Diagnosis edit code list under the ICD–10 MCE Version 39, effective October 1, 2021.

e. Unspecified Codes

As discussed in section II.D.12.c. of the preamble of the proposed rule and this final rule, we requested public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we were considering adopting for FY 2022. In connection with that request, we also requested public comments on the potential creation of a new MCE code edit involving these ''unspecified'' codes for FY 2022. Specifically, this MCE code edit could trigger when an ''unspecified'' diagnosis code currently designated as either a CC or MCC, that includes other codes available in that code subcategory that further specify the anatomic site, is entered. We referred the reader to table 6P.3a associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for the list of unspecified diagnosis codes that would be subject to this edit. We stated that this edit could signal to the provider that a more specific code is available to report. We also stated we believed this edit aligns with documentation improvement efforts and leverages the specificity within ICD–10. As part of our request for comment on the potential creation of this new MCE code edit for these ''unspecified'' codes, we noted we were interested in comments on how this MCE code edit may be developed for FY 2022 to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

Comment: Many commenters expressed support for the creation of a new ''unspecified'' code edit where other codes in the subcategory (family) exist describing laterality, however, the commenters stated that the edit should be phased in with a subset of the ''unspecified'' codes at a time. The commenters also stated this approach would help provide training time for coding professionals and clinical documentation program staff on the potential changes to the severity level for the unspecified codes. A commenter stated a phased approach could also better prepare teams to adapt to potential operational challenges in addressing these edits industry wide. Another commenter who expressed support stated they agreed with the list of codes, with the exception of the neoplasm codes.

Another commenter expressed support for the creation of a new ''unspecified'' code MCE edit to align with the potential change to the severity level designation of ''unspecified'' diagnosis codes to a NonCC when there are other codes available in that code subcategory that further specify the anatomic site.

Other commenters stated they appreciated CMS assisting hospitals to more accurately code and not negatively impact MS–DRG group assignment, however according to the commenters, edits at the time of claim submission will add significant administrative burden to hospitals. According to the commenters, it would necessitate every case being routed from billing staff back to coding staff and then coding staff having to query physicians to amend the medical record with specificity. The commenters stated they did not object to CMS instructing providers to no longer report unspecified codes if it was done in concert with updates to the coding guidelines. Commenters suggested a delay in the implementation of the edit to allow the Cooperating Parties for ICD–10 time to update the current guidelines to include reporting specificity (for example laterality) based on non-physician clinical staff documentation.

Other commenters recommended that CMS conduct an analysis of how often the unspecified codes that were listed in Table 6P.2a in association with the proposed rule are reported and how many resources they consume.

Response: In response to the recommendation that CMS implement the edit using a phased approach to allow time for staff to prepare for potential changes to the severity level for the unspecified codes, we do not believe that a phased approach is necessary. As discussed in section II.D.12.c. of the preamble of this final rule, we are not finalizing any changes to the severity level designations for the unspecified codes that were subject to the potential change and listed in Table 6P.2a in association with the proposed rule (available via the internet on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*), at this time. As also discussed in section II.D.12.c. of the preamble of this final rule, in response to public comments, we removed the diagnosis codes describing neoplasm of an unspecified site from the list of codes that were being considered for possible adoption of a change to the severity level designation.

In response to commenters' concerns that an edit for ''unspecified'' codes would create an administrative burden to hospitals, as it may result in additional physician queries, we note that the intent of the edit is not to create the need for physician queries. In anticipation of such potential concerns and suggested updates to the coding guidelines, we note that, as one of the four Cooperating Parties for ICD–10, we considered these issues in advance and updated the guidelines accordingly, as shown in the FY 2022 ICD–10–CM Official Guidelines for Coding and Reporting (available via the internet on the CMS website at: *https://www.cms.gov/medicare/icd-10/2022-icd-10-cm*) and discussed in section II.D.12.c. of the preamble of this final rule. Specifically, as stated in section I.B.13. of the guidelines, ''When laterality is not documented by the patient's provider, code assignment for the affected side may be based on medical record documentation from other clinicians. If there is conflicting medical record documentation regarding the affected side, the patient's attending provider should be queried for clarification. Codes for ''unspecified'' side should rarely be used, such as when the documentation in the record is insufficient to determine the affected side and it is not possible to obtain clarification.'' Corresponding revisions to the guidelines can also be found in section I.B.14. Therefore, we believe that the updates made to the coding guidelines address that aspect of the commenters' concerns.

With respect to the commenters' recommendation that CMS conduct an analysis of how often the unspecified codes that were listed in Table 6P.2a are reported and how many resources they consume, we refer to the discussion in section II.D.12.c. of the preamble of this final rule, and note that Table 6P.2a associated with the proposed rule specifically provided this information.

After consideration of the public comments received, we are finalizing the implementation of a new code edit for ''unspecified'' codes, where there are other codes available in that code subcategory that further specify the anatomic site. As noted previously, the severity level of the unspecified diagnosis codes is unaffected and therefore this edit does not affect the payment the provider is eligible to receive. We also note that, in consideration of commenters' concerns that more time is needed to educate providers, the implementation date for this new edit is April 1, 2022. As such, we are finalizing the new edit for FY 2022, effective with discharges on and after April 1, 2022. Stakeholders can anticipate future information regarding

an updated version of the *ICD–10 Medicare Severity Diagnosis Related Group (MS–DRG) GROUPER Software and Medicare Code Editor (MCE) ICD–10 Software* to be released by February 1, 2022 via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

We are finalizing a new ''Unspecified Code Edit: to read as follows:

20. Unspecified Code Edit

Unspecified codes exist in the ICD–10–CM classification for circumstances when documentation in the medical record does not provide the level of detail needed to support reporting a more specific code. However, in the inpatient setting, there should generally be very limited and rare circumstances for which the laterality (right, left, bilateral) of a condition is unable to be documented and reported.

The following pages contain the list of unspecified ICD–10–CM diagnosis codes for which there is a more specific code to identify laterality (right, left, bilateral) within that code family.''

The list of codes subject to this edit are identified in Table 6P.3a associated with this final rule. In addition to the removal of the neoplasm codes from the unspecified codes list discussed previously, we also removed the following codes from consideration in response to public comments and further internal review, as discussed previously in connection with the potential change to the severity level designation.

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ICD-10-CM Code	Code Description
S02.113A	Unspecified occipital condyle fracture, initial encounter for closed fracture
S02.113B	Unspecified occipital condyle fracture, initial encounter for open fracture
S02.113K	Unspecified occipital condyle fracture, subsequent encounter for fracture with nonunion
S02.118A	Other fracture of occiput, unspecified side, initial encounter for closed fracture
S02.118B	Other fracture of occiput, unspecified side, initial encounter for open fracture
S02.118K	Other fracture of occiput, unspecified side, subsequent encounter for fracture with nonunion
S02.119A	Unspecified fracture of occiput, initial encounter for closed fracture
S02.119B	Unspecified fracture of occiput, initial encounter for open fracture
S02.119K	Unspecified fracture of occiput, subsequent encounter for fracture with nonunion
S04.819A	Injury of olfactory [1st] nerve, unspecified side, initial encounter
S04.9XXA	Injury of unspecified cranial nerve, initial encounter
S32.9XXA	Fracture of unspecified parts of lumbosacral spine and pelvis, initial encounter for closed fracture
S32.9XXB	Fracture of unspecified parts of lumbosacral spine and pelvis, initial encounter for open fracture
S32.9XXK	Fracture of unspecified parts of lumbosacral spine and pelvis, subsequent encounter for fracture with nonunion
S36.209A	Unspecified injury of unspecified part of pancreas, initial encounter
S36.249A	Minor laceration of unspecified part of pancreas, initial encounter
S36.259A	Moderate laceration of unspecified part of pancreas, initial encounter
S36.269A	Major laceration of unspecified part of pancreas, initial encounter
S36.509A	Unspecified injury of unspecified part of colon, initial encounter
S36.90XA	Unspecified injury of unspecified intra-abdominal organ, initial encounter
S37.90XA	Unspecified injury of unspecified urinary and pelvic organ, initial encounter
S78.911A	Complete traumatic amputation of right hip and thigh, level unspecified, initial encounter
S78.921A	Partial traumatic amputation of right hip and thigh, level unspecified, initial encounter
S82.001N	Unspecified fracture of right patella, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion
S82.001R	Unspecified fracture of right patella, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with malunion
T27.3XXA	Burn of respiratory tract, part unspecified, initial encounter
T27.7XXA	Corrosion of respiratory tract, part unspecified, initial encounter

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When a code from the list displayed in Table 6P.3a is entered on the claim, the edit will be triggered. It is the provider's responsibility to determine if a more specific code from that subcategory is available in the medical

record documentation by a clinical provider. If, upon review, additional information to identify the laterality from the available medical record documentation by any other clinical provider is unable to be obtained or there is documentation in the record that the physician is clinically unable to determine the laterality because of the nature of the disease/condition, then the provider must enter that information into the remarks section. Specifically, the provider may enter ''UNABLE TO DET LAT 1'' to identify that they are unable to obtain additional information to specify laterality or they may enter ''UNABLE TO DET LAT 2'' to identify that the physician is clinically unable to determine laterality.'' This action and language will enable the Medicare Administrative Contractor (MAC) to bypass the edit and process the claim accordingly. If there is no language entered into the remarks section as to the availability of additional information to specify laterality and the provider submits the claim for processing, the claim would then be returned to the provider.

f. Future Enhancement

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38053 through 38054) we noted the importance of ensuring accuracy of the coded data from the reporting, collection, processing, coverage, payment and analysis aspects. Subsequently, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20235) we stated that we engaged a contractor to assist in the review of the limited coverage and non-covered procedure edits in the MCE that may also be present in other claims processing systems that are utilized by our MACs. The MACs must adhere to criteria specified within the National Coverage Determinations (NCDs) and may implement their own edits in addition to what is already incorporated into the MCE, resulting in duplicate edits. The objective of this review is to identify where duplicate edits may exist and to determine what the impact might be if these edits were to be removed from the MCE.

We have also noted that the purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As we indicated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41228), we are considering whether the inclusion of coverage edits in the MCE necessarily aligns with that specific goal because the focus of coverage edits is on whether or not a particular service is covered for payment purposes and not whether it was coded correctly.

As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we have discussed in prior rulemaking, we recognize a need to further examine the current list of edits and the definitions of those edits. We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the MS–DRG Classification Change Mailbox located at *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2021.

15. Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this final rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule, we received a request to examine the MS–DRG hierarchy within MDC 05 (Diseases and Disorders of the Circulatory System). The requestor stated its request to review the hierarchy within MDC 05 was based on the relative weights within each MS–DRG subdivision which they stated are supportive of higher position within the hierarchy. The requestor stated that when multiple procedures are performed, it is

reasonable for providers to be compensated for the highest weighted procedure. The requestor did not specify which data year it analyzed to identify the relative weights. As discussed in the proposed rule and previously in this section, in reviewing the surgical hierarchy, we weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG), not the relative weights of each MS–DRG as suggested by the requestor, to determine average resource consumption for the surgical class; therefore, consistent with our annual process, we stated we used the methodology as described previously to review the surgical hierarchy within MDC 05.

Based on our review of the surgical hierarchy within MDC 05 in response to this request, and in response to the request we received to review the MS–DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation as discussed in section II.D.5.e. of the preamble of the proposed rule and this final rule, we proposed to revise the surgical hierarchy for the MS–DRGs in MDC 05 for FY 2022. Specifically, we proposed to sequence MS–DRGs 231–236 above MS–DRGs 222–227 and below MS–DRGs 216–221, sequence MS–DRGs 222–227 above MS–DRGs 266–227 and below MS–DRGs 231–236, sequence MS–DRGs 266–267 above MS–DRGs 268–269 and below MS–DRGs 222–227, sequence MS–DRGs 228–229 above MS–DRGs 319–320 and below MS–DRGs 268–269.

Our proposal for Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 39 is illustrated in the following table.

Proposed Surgical Hierarchy: MDC 05	
215	Other Heart Assist System Implant
216 – 221	Cardiac Valve and Other Major Cardiothoracic Procedures
231 – 236	Coronary Bypass
222 – 227	Cardiac Defibrillator Implant
266 – 267	Endovascular Cardiac Valve Replacement and Supplement Procedures
268 – 269	Aortic and Heart Assist Procedures
228 – 229	Other Cardiothoracic Procedures
319 – 320	Other Endovascular Cardiac Valve Procedures

Comment: Commenters supported our proposal. A commenter stated that this reordering of the surgical hierarchy appears reasonable. However, other commenters opposed portions of our proposal and requested that CMS reconsider and maintain MS–DRGs 222–227 (Cardiac Defibrillator Implant) as higher in the surgical hierarchy than MS–DRGs 231–236 (Coronary Bypass). These commenters stated that if CABG procedures are considered in the surgical hierarchy before procedures to insert a cardiac defibrillator implant, the majority of the cases would probably be assigned to MS–DRGs 235 and 236 (Coronary Bypass without Cardiac Catheterization with and without MCC, respectively), which would not account for the higher cost of the defibrillators.

Another commenter stated while they agreed with the proposal to sequence MS–DRGs 231–236 above MS–DRGs 228 and 229 (Other Cardiothoracic Procedures), they stated that CMS did not provide specific discussion regarding the more extensive re-sequencing in MDC 05 and suggested that CMS to hold on these revisions to the surgical hierarchy pending a clear and specific rationale for each, to which the public can respond. Another commenter proposed an alternative option by stating that it seemed more appropriate to sequence MS–DRG 245 (AICD Generator Procedures) above MS–DRGs 270—272 (Other Major Cardiovascular Procedures) and below MS–DRGs 228–229 (Other Cardiothoracic Procedures) and to sequence MS–DRGs 270–272 above MS–DRGs 319–320 (Other Endovascular Cardiac Valve Procedures) and below MS–DRG 245. However, this commenter did not provide any rationale for their alternative option.

Response: We appreciate the commenters' support.

In response to the comment that CMS did not provide specific discussion, we note that we indicated in the proposed rule and previously in this section, that in reviewing the surgical hierarchy, we weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. Consistent with our annual process, we stated we used the methodology as described previously to review the surgical hierarchy within MDC 05.

To compare and analyze the impact of our suggested modifications in response to the commenter's suggestion that we sequence MS–DRGs 222–227 above MS–DRGs 231–236, we reviewed the surgical hierarchy once again. Specifically, we examined the redistribution of cases that is anticipated to occur as a result of the proposal to move MS–DRGs 231–236 (Coronary Bypass) above MS–DRGs 222–227 (Cardiac Defibrillator Implant) in the surgical hierarchy of MDC 05 for Version 39 of the ICD–10 MS–DRGs. We processed the claims data from the March 2020 update of the FY 2019 MedPAR file through the ICD–10 MS–DRG GROUPER Version 38 and then processed the same claims data through the ICD–10 MS–DRG GROUPER Version 39 for comparison. The number of cases from this comparison that result in different MS–DRG assignments is the number of the cases that are anticipated to potentially shift or be redistributed. Our findings are shown in the following table.

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Version 38 MS-DRG	Description	Version 39 MS-DRG	Description	Counts
222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or shock with MCC	223	Cardiac DefibrillatorIimplant with Cardiac Catheterization with AMI, HF or shock without MCC	5
		231	Coronary Bypass with PTCA with MCC	10
		233	Coronary Bypass with Cardiac Catheterization with MCC	74
223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or shock without MCC	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or shock with MCC	184
		233	Coronary Bypass with Cardiac Catheterization with MCC	2
		234	Coronary Bypass with Cardiac catheterization without MCC	7
224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF or shock with MCC	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or shock with MCC	107
		223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or shock without MCC	106
		231	Coronary Bypass with PTCA with MCC	2
		233	Coronary Bypass with Cardiac catheterization with MCC	56
225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF or shock without MCC	234	Coronary Bypass with Cardiac Catheterization without MCC	16
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	235	Coronary Bypass without Cardiac Catheterization with MCC	67
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	427
		236	Coronary Bypass without Cardiac Catheterization without MCC	24

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We found that a small number of cases, 67 cases and 24 cases, are anticipated to potentially shift or be

redistributed into MS–DRGs 235 and 236, respectively.

As we did with March 2020 update of the FY 2019 MedPAR file, we then examined the redistribution of cases that is anticipated to occur by processing the claims data, this time from the September 2020 update of the FY 2020 MedPAR file through the ICD–10 MS–DRG GROUPER Version 38 and then processed the same claims data through the ICD–10 MS–DRG GROUPER Version 39 for comparison. Our findings are shown in the following table.

BILLING CODE 4120–01–P

Version 38 MS-DRG	Description	Version 39 MS-DRG	Description	Counts
222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock with MCC	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock without MCC	4
		231	Coronary Bypass with PTCA with MCC	19
		233	Coronary Bypass with Cardiac Catheterization with MCC	127
223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock without MCC	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock with MCC	264
		232	Coronary Bypass with PTCA without MCC	1
		233	Coronary Bypass with Cardiac Catheterization with MCC	1
		234	Coronary Bypass with Cardiac Catheterization without MCC	11
224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI HF or Shock with MCC	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock with MCC	250
		223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock without MCC	198
		231	Coronary Bypass with PTCA with MCC	9

		233	Coronary Bypass with Cardiac Catheterization with MCC	84
225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI HF or Shock without MCC	232	Coronary Bypass with PTCA without MCC	1
		234	Coronary Bypass with Cardiac Catheterization without MCC	19
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	231	Coronary Bypass with PTCA with MCC	1
		235	Coronary Bypass without Cardiac Catheterization with MCC	84
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	610
		236	Coronary Bypass without Cardiac Catheterization without MCC	23

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Similarly, we found that a small number of cases, 84 cases and 23 cases, are anticipated to potentially shift or be redistributed into MS–DRGs 235 and 236, respectively.

Our clinical advisors reviewed these data and the commenter's concerns and state, as in open concomitant surgical ablation procedures, when a CABG procedure is performed along with the insertion of a cardiac defibrillator implant, the CABG component of the procedure is more technically complex than the procedure to insert the cardiac defibrillator implant. The redistribution of the small number of cases to MS–DRGs 235 and 236 as a result of the proposed hierarchy change more appropriately reflects resource utilization when multiple cardiac procedures are performed and will result in the most suitable MS–DRG assignment.

In the absence of a compelling rationale to further modify our proposal as suggested by the alternate option provided by the commenter, our clinical advisors continue to state that the proposed revision to the surgical hierarchy leads to a grouping that is more coherent and better accounts for the resources expended to address the more complex procedures from other cases redistributed during the hierarchy change.

Therefore, after consideration of the public comments we received, we are finalizing the proposed changes to the surgical hierarchy for the MS–DRGs in MDC 05 as illustrated in the table for the surgical hierarchy within Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 39, without modification, for FY 2022.

16. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.* The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.*

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously stated process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of

recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed during the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2022 at a public meeting held on September 8–9, 2020 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 09, 2020.

The Committee held its 2021 meeting on March 9–10, 2021. The deadline for submitting comments on the code proposals being considered for an October 1, 2021 implementation was April 9, 2021. It was announced at this meeting that any new diagnosis and procedure codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by June 2021 would be included in the October 1, 2021 update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. As discussed in earlier sections of the preamble of this final rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A—New Diagnosis Codes, Table 6B—New Procedure Codes, Table 6C—Invalid Diagnosis Codes, Table 6D—Invalid Procedure Codes, Table 6E—Revised Diagnosis Code Titles and Table 6F—Revised Procedure Code Titles for this final rule, which are available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we make the code titles available for the IPPS proposed and final rules, they are not subject to comment in the proposed or final rule. Because of the length of these tables, they are not published in the Addendum to the proposed or final rule. Rather, they are available via the internet as discussed in section VI. of the Addendum to the proposed rule and this final rule.

Recordings for the virtual meeting discussions of the procedure codes at the Committee's September 8–9, 2020 meeting and the March 9–10, 2021 meeting can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*. The materials for the discussions relating to diagnosis codes at the September 8–9, 2020 meeting and March 9–10, 2021 meeting can be found at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html*. These websites also provide detailed information about the Committee, including information on requesting a new code, participating in a Committee meeting, timeline requirements and meeting dates.

We encourage commenters to submit questions and comments on coding issues involving diagnosis codes via Email to: *nchsicd10cm@cdc.gov*.

Questions and comments concerning the procedure codes should be submitted via Email to: *ICDProcedureCodeRequest@cms.hhs.gov*.

We stated in the proposed rule that as a result of the ongoing COVID–19 public health emergency, the CDC implemented six new diagnosis codes describing conditions related to COVID–19 into the ICD–10–CM effective with discharges on and after January 1, 2021. The diagnosis codes are

ICD-10-CM Code	Code Description
J12.82	Pneumonia due to coronavirus disease 2019
M35.81	Multisystem inflammatory syndrome (MIS)
M35.89	Other specified systemic involvement of connective tissue
Z11.52	Encounter for screening for COVID-19
Z20.822	Contact with and (suspected) exposure to COVID-19
Z86.16	Personal history of COVID-19

We refer the reader to the CDC web page at *https://www.cdc.gov/nchs/icd/icd10cm.htm* for additional details regarding the implementation of these new diagnosis codes.

As we discussed in the proposed rule, we provided the MS–DRG assignments for the six diagnosis codes effective with discharges on and after January 1, 2021, consistent with our established process for assigning new diagnosis codes. Specifically, we review the predecessor diagnosis code and MS–DRG assignment most closely associated with the new diagnosis code, and consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, and the resources utilized for the specific condition/diagnosis. We note that this process does not automatically result in the new diagnosis code being assigned to the same MS–DRG as the predecessor code. The assignments for the previously listed diagnosis codes are reflected in Table 6A—New Diagnosis Codes associated with the proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). As with the other new diagnosis codes and MS–DRG assignments included in Table 6A of the proposed rule, we solicited public comments on the most appropriate MDC, MS–DRG, and severity level assignments for these codes for FY 2022, as well as any other options for the GROUPER logic.

We did not receive any comments opposing the MDC, MS–DRG, and severity level assignments for the listed codes and are therefore, finalizing the assignments as reflected in Table 6A—New Diagnosis Codes in association with this final rule.

In addition, we noted in the proposed rule that CMS implemented 21 new procedure codes describing the introduction or infusion of therapeutics, including monoclonal antibodies and vaccines for COVID–19 treatment, into the ICD–10–PCS effective with

discharges on and after January 01, 2021. The 21 procedure codes listed in this section of this rule are designated as non-O.R. and do not affect any MDC or MS–DRG assignment as shown in the following table.

BILLING CODE 4120–01–P

ICD-10-PCS Code	Description	O.R.	MDC	MS-DRG
XW013H6	Introduction of other new technology monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW013K6	Introduction of leronlimab monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW013S6	Introduction of COVID-19 vaccine dose 1 into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW013T6	Introduction of COVID-19 vaccine dose 2 into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW013U6	Introduction of COVID-19 vaccine into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW023S6	Introduction of COVID-19 vaccine dose 1 into muscle, percutaneous approach, new technology group 6	N		
XW023T6	Introduction of COVID-19 vaccine dose 2 into muscle, percutaneous approach, new technology group 6	N		
XW023U6	Introduction of COVID-19 vaccine into muscle, percutaneous approach, new technology group 6	N		
XW033E6	Introduction of etesevimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	N		
XW033F6	Introduction of bamlanivimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	N		
XW033G6	Introduction of REGN-COV2 monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	N		
XW033H6	Introduction of other new technology monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	N		
XW033L6	Introduction of CD24Fc immunomodulator into peripheral vein, percutaneous approach, new technology group 6	N		
XW043E6	Introduction of etesevimab monoclonal antibody into central vein, percutaneous approach, new technology group 6	N		
XW043F6	Introduction of bamlanivimab monoclonal antibody into central vein, percutaneous approach, new technology group 6	N		
XW043G6	Introduction of REGN-COV2 monoclonal antibody into central vein, percutaneous approach, new technology group 6	N		
XW043H6	Introduction of other new technology monoclonal antibody into central vein, percutaneous approach, new technology group 6	N		
XW043L6	Introduction of CD24Fc immunomodulator into central vein, percutaneous approach, new technology group 6	N		
XW0DXM6	Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6	N		
XW0G7M6	Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6	N		
XW0H7M6	Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6	N		

BILLING CODE 4120–01–C

The ICD–10 MS–DRG assignment for cases reporting any one of the 21 procedure codes is dependent on the reported principal diagnosis, any secondary diagnoses defined as a CC or MCC, procedures or services performed, age, sex, and discharge status. The 21 procedure codes are reflected in Table 6B—New Procedure Codes associated with the proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.) As with the other new procedure codes and MS–DRG assignments included in Table 6B of the proposed rule, we solicited public comments on the most appropriate MDC, MS–DRG, and operating room status assignments for these codes for FY 2022, as well as any other options for the GROUPER logic.

We did not receive any comments opposing the MDC, MS–DRG, and operating room status assignments for the listed codes and are therefore, finalizing the assignments as reflected in Table 6B—New Procedure Codes in association with this final rule.

In the proposed rule we also noted that Change Request (CR) 11895, Transmittal 10654, titled ''Fiscal Year (FY) 2021 Annual Update to the Medicare Code Editor (MCE) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) and Procedure Coding System (ICD–10–PCS)'', was issued on March 12, 2021 (available via the internet on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10654cp*) regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version 38.1, effective with discharges on and after January 1, 2021, reflecting the new diagnosis and procedure codes. The updated software, along with the updated ICD–10 MS–DRG V38.1 Definitions Manual and the Definitions of Medicare Code Edits V38.1 manual is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 3 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. Historically, this 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Pub. L. 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requestor during the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. Meeting participants and those reviewing the Committee meeting materials are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants of the Committee meeting and those reviewing the Committee meeting materials are encouraged to comment on all such requests. There were no code requests approved for an expedited April 1, 2021 implementation at the September 8–9, 2020 Committee meetings. Therefore, there were no new codes implemented April 1, 2021.

We noted in the proposed rule that during the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee meeting we announced our consideration of an April 1 implementation date for ICD–10–CM diagnosis and ICD–10–PCS procedure code updates, in addition to the current October 1 annual update for ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes. We stated that this April 1 code update would be in addition to the existing April 1 update under section 1886(d)(5)(k)(vii) of the Act for diagnosis or procedure code

revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. As explained during the March 9–10, 2021 meeting, we stated we believe this additional April 1 implementation date for new codes would allow for earlier recognition of diagnoses, conditions, and illnesses as well as procedures, services, and treatments in the claims data. We also stated we believe this earlier recognition would be beneficial for purposes of reporting, data collection, tracking clinical outcomes, claims processing, surveillance, research, policy decisions and data interoperability. We noted, as previously summarized, that in 2005, in connection with the implementation of the current April 1 update for diagnosis or procedure code revisions for purposes of the new technology add-on payment process, stakeholders expressed concerns with an April 1 update, specifically with regard to the time needed to update hospital systems and obtain new code books and coding software. We further stated we believe that the advances in technology that have occurred since that time, including the use of electronic health records (EHRs), electronic coding books, and updated encoder software that are now utilized by the majority of providers, would alleviate those concerns and make a broader April 1 update more feasible today. Consistent with our established process for the existing April 1 update under section 1886(d)(5)(k)(vii) of the Act, if adopted, any new ICD–10 code updates finalized for implementation on the following April 1 would be announced in November of the prior year, which would provide a 4-month timeframe for the public to receive notice about the diagnosis and/or procedure code updates with respect to the codes, code descriptions, code designations (severity level for diagnosis codes or O.R. status for procedure codes) and code assignment under the ICD–10 MS–DRGs. As discussed during the March 9–10, 2021 meeting, all April 1 code update files would be made publicly available by February 1, providing a 2-month timeframe for providers to incorporate systems updates. We also noted in the proposed rule that we do not anticipate any need for code book publishers to issue new code books as a result of an April 1 code update, if adopted. Rather, as was done in the past at the publisher's discretion, supplemental pages containing the code update information were made available and sent to purchasers of the code book products. We further noted that historically, coders would hand-write any updates or notes directly into their code books. In addition, we stated in the proposed rule that with the availability of electronic code book files, we would anticipate any April 1 code updates, if adopted, could be reasonably completed in the allotted timeframe. For these same reasons, we also stated we do not believe a 5-month time period would continue to be needed to update providers' systems to reflect newly approved coding changes. We further noted that if an April 1 update were to be adopted, it could be through a phased approach, such that initially, the number and nature of the code updates would be fewer and less comprehensive as compared to the existing October 1 update. For example, it was discussed during the meeting that consideration could first be given to proposals identified as ''Addenda''. For diagnosis codes, the proposed addenda update typically consist primarily of minor revisions to the Index and Tabular List, such as corrections to typos and changes to instructional notes. For procedure codes, the proposed addenda update typically consist primarily of minor revisions to the Index and Tables, such as adding or deleting entries to describe a body part or approach value or making changes to the Substance and Device Keys. We stated we would use our established process to implement an April 1 code update, which would include presenting proposals for April 1 consideration at the September ICD–10 Coordination and Maintenance Committee meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new GROUPER release information. We also stated that under our contemplated process, requestors would indicate whether they are submitting their code request for consideration for an April 1 implementation date, if adopted, or an October 1 implementation date. We further stated that the ICD–10 Coordination and Maintenance Committee would make efforts to accommodate the requested implementation date for each request submitted. However, the Committee would determine which requests would be presented for consideration for an April 1 implementation date or an October 1 implementation date. We refer the reader to the Agenda packet from the meeting at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional information regarding this announcement and our request for comments.

We stated that if this new April 1 implementation date is adopted, we would assign the codes approved for the April 1 update to an MS–DRG(s) using our established process for GROUPER assignments for new diagnosis and procedure codes. Specifically, consistent with our established process for assigning new diagnosis and procedure codes, we would review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we would consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We noted that this process would not automatically result in the new diagnosis or procedure code being assigned to the same MS–DRG or having the same designation as the predecessor code.

Comment: Several commenters expressed support for an April 1 update, in addition to the October 1 annual update. The commenters encouraged the CDC/NCHS and CMS to develop policies that expedite the assignment of new diagnosis and procedure codes to meet the needs of clinical advancements. Other commenters commended CMS for its ongoing efforts to improve the timeliness of coding and payment decisions for new technologies, and expressed their support for an April 1 update as a key piece of those efforts. Some commenters stated that more timely coding updates will allow CMS additional time to analyze how therapies are utilized in the inpatient setting and will improve the completeness of claims data capture that includes volume, length of stay, and cost data that should lead to better informed rate-setting methodologies. According to the commenters, expedited coding could potentially reduce the amount of time required to stabilize payments to hospitals for utilizing first-in-class therapies. Many commenters agreed that an additional update for ICD–10 codes would allow for earlier recognition of diagnoses, conditions, and illnesses as well as procedures, services, and treatments in the claims data. A commenter stated they strongly support the timely and specific data capture of ICD–10–CM and ICD–10–PCS codes for the purposes of tracking rare diseases, research, tracking of social determinants of health (SDOH), advancing medicine through quality data, and for public health. This

commenter stated that processes are already in place for code updates in October and this new proposed update, if adopted, would not be a departure from that process, but would yield more timely implementation of important codes. According to the commenter, this would lessen the burden of putting all updates into one annual update in October. Another commenter emphasized that the availability of an April 1 process for updating and implementing new technology related ICD–10–CM and ICD–10–PCS codes is especially important for encouraging access to transformative therapies, including novel cell and gene therapies-such as TIL therapies and chimeric antigen receptor (CAR) T-cell therapies. According to the commenter, these new technologies target some of the most serious medical conditions imaginable, offer treatment that is highly personalized to each individual patient, and carry vast transformational potential in terms of patient care and clinical outcomes. The commenter stated that to the extent CMS and CDC/NCHS are considering a phased-in implementation of the April 1 code implementation as the agencies suggested during the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee meeting, the commenter strongly urged the agencies to ensure that if adopted, the initial implementation permit new technology codes related to novel cell and gene therapies to be implemented effective April 1, as well as October 1. The commenter asserted that these types of therapies are limited in number and there is a profound and unique need for the prompt availability of such therapies in order to encourage more timely beneficiary access to these potentially lifesaving new therapies.

Another commenter expressed its support for the approach to integrating the potential April 1 implementation of new codes into the IPPS based on the MS–DRG policies in effect under the established process. According to the commenter, if adopted, this April 1 implementation option could offer several specific advantages for MS–DRG assignment for technologies receiving market approval too late to have coding and payment in place on October 1, particularly related to applications for new technology add-on payments. The commenter stated their belief that it also maintains the current public notice and comment rulemaking process for proposing, considering, and implementing decisions affecting MS–DRG assignments, with the additional flexibility to establish policies in anticipation of codes implemented on April 1. This commenter stated that its support for an April 1 implementation presumes that conditional decisions are established through prior notice and comment rulemaking.

In response to the request for feedback on what criteria or factors should be taken into consideration for determining whether to consider a code request for an April 1 or October 1 implementation date, some commenters stated CMS should consider expedited access. Specifically, according to the commenters, CMS should work with manufacturers to identify an implementation date that most closely aligns with approval by the Food and Drug Administration as the implementation date of the new procedure code and consideration for a new technology add-on payment (NTAP) as well. By doing so, the commenters indicated CMS will take steps to align the IPPS and provider reimbursement with the pace of innovation. The commenters also stated CMS should consider new codes that are related to new therapies that will be up for regulatory approval, or for diagnoses that are new and important to public health (such as those from the COVID–19 PHE). The commenters stated it is better to have coding in place before, and certainly as soon as, a product is approved, and sooner rather than later when an emerging public health issue is identified. A commenter suggested that if a sponsor anticipates receiving approval from the Food and Drug Administration in the third quarter of the year, the ICD–10 code update could occur in April. Similarly, if an approval is anticipated in the first quarter, then the ICD–10 code update could occur October 1. According to the commenter, the Committee should strive to make data collection as accurate and timely as possible.

Other commenters recommended that the Committee should consider the goal of facilitating and promoting patient access and well-being. These commenters stated the Committee should prioritize updates for which significant public feedback and corresponding medical literature indicate a pronounced need for expedited implementation to further understanding of particular conditions and advance clinical research on potential treatment options.

A few commenters stated that although the coding changes associated with COVID–19 under the PHE have demonstrated it is possible to implement more frequent coding updates that are limited in number, significant adjustments were needed to incorporate the updates and resulted in operational issues for hospitals. These commenters suggested that CMS consider limiting the number of codes approved with respect to adoption of an April 1 implementation date for ICD–10–CM diagnosis and ICD–10–PCS procedure code updates, in addition to the current October 1 annual update. In addition to limited updates, other commenters specifically recommended that if adopted, April 1 code updates should be restricted to simple, straightforward changes, such as the Addenda proposals involving proposed updates to the Alphabetic Index and Tabular List of Diseases and the correction of errors. The commenters stated that clear and consistent criteria should be applied to determine the need for new codes such as consideration of a new or emerging disease/illness/condition, an innovative technology that is unable to be reported with existing codes, or codes related to proposals that have been presented at the Coordination and Maintenance Committee meetings more than one time as a repeat proposal due to public comments and feedback.

Another commenter stated that consideration of an April 1 implementation should include a public process, similar to HCPCS and rulemaking, that allows stakeholders to weigh in on both procedure code creation and MS–DRG assignment and provides stakeholders with CMS reasoning behind its decisions.

With respect to the request for feedback on how an April 1 implementation date may affect business processes, a few commenters stated their belief that, initially, there may be some increased work to ensure that the April 1 codes released (and the MS–DRG grouping assignments) are up to date in their systems. The commenters stated this effort would include checking with software vendors to ensure that they are also updating their software for the new codes and groupings. A commenter stated that the benefits of adding the new release cycle, however, will be well worth the time and resource investment at the beginning. According to the commenter, having codes released in a timely manner so that data can be collected sooner rather than later will give insights that could lead to a reduction in burden elsewhere. The commenter stated that modernization to existing codes so they match current physician documentation terminology and practices will also reduce coders' work downstream over time.

A commenter stated that the addition of another cycle will enable ICD–10–CM diagnosis codes to be released in a more

timely manner to reflect new diseases or conditions and facilitate clinical research, as well as data collection, all of which would ultimately improve patient care. This commenter stated the adoption of an April 1 implementation is particularly important for diagnosis codes, since proposals discussed at the March meetings generally do not go into effect until October 1 of the following year, resulting in an 18-month delay. According to the commenter, more timely releases of diagnosis codes would be crucial in the area of advanced cell therapy research, as it would facilitate better identification and tracking for this distinct subset of patients, which can advance clinical understanding and subsequently improve diagnostic and treatment standards.

Some commenters who supported an April 1 implementation date also expressed concerns with having twice a year code updates. Specifically, commenters noted concerns with payor/vendor updates being incorporated timely, training and education, and the ability to comment on MS–DRG assignments. The commenters also requested additional clarity and transparency on how the agencies intend to communicate timelines and decisions on which coding requests would be considered for April 1 versus October 1 during the ICD–10 Coordination and Maintenance Committee meetings.

A few commenters opposed consideration of the April 1 implementation date in addition to the October 1 annual update, for similar reasons described previously, as to how it may affect business processes. A commenter stated it will be a work intensive process in terms of systems updates, training time, and data comparison. A few commenters indicated they did not support an April 1 implementation and corresponding updated Grouper release without a comment period. A commenter stated the current GROUPER allows for a comment period prior to implementation in October (of the new GROUPER) and it is important to recognize that revisions may be made from the proposed and final GROUPER considerations especially for new codes. The commenter provided the example that for FY 2021 rulemaking, the comment period was important to allow CMS to consider provider feedback on the proposed MCC/CC designations for new ICD–10–CM diagnosis codes which also provided specificity for the grades of Cytokine Release Syndrome which were all proposed to be NonCC severity level. The commenter stated that after review of the comments, the diagnosis codes for Grades 3, 4, 5 (D89.833, D89.834, D89.835) were revised and finalized by CMS to a CC Severity Level. This commenter also stated that the ICD–10–CM and ICD–10–PCS code sets are not limited to the use of CMS providers as all providers utilize the ICD–10 codes and may not be able to turn around code updates as quickly as CMS. The commenter further stated that the code set is used to update computer systems, contracts, reimbursement systems and is not limited to MS–DRGs only. A few commenters expressed concern with operational challenges and stated that there are providers and commercial payors that currently do not incorporate the annual update timely, so it is important for systems to be able to adapt to the version of the code set in place for the provider. The commenters stated a second release date in April would result in addressing payor non-compliance twice a year. Other commenters who opposed adoption of an April 1 implementation date for code updates stated it would be costly for providers, payors, insurance companies and all healthcare organizations as it would involve purchase of code books, code tables, encoder updates and other related materials twice per year rather than once per year.

A commenter who opposed the potential adoption of an April 1 code update submitted the following questions or statements about the process.

1. What is the process and/or criteria that will be used in identifying which codes will be implemented in April versus October? Is it solely based on the date the submitter requested?

2. Will both April and October proposed codes be covered in the ICD–10 Coordination and Maintenance Committee meetings?

3. Right now, 99% of the codes proposed in March are not for the upcoming October 1 release but the following October 1 release (two years away). Will adding an April update increase the turnaround time for implementing a new code, that is, reducing it to a 1-year proposal to implementation versus a 2-year proposal to implementation?

4. What will be the effective dates of the codes and guidelines added in April? Will this alter the effective dates of the October codes and guidelines? Example:

April codes/guidelines—effective April 1, 2022 to September 30, 2022
October codes/guidelines—effective October 1, 2022 to March 31, 2023
OR
April codes/guidelines—effective April 1, 2022 to March 31, 2023
October codes/guidelines—effective October 1, 2022 to September 30, 2023

5. Can you provide examples of codes that would require immediate implementation, outside of a public health emergency? For 2020, there were at least three separate code updates outside the April and October ''regular'' dates. If it is essential that a code be added to the classification, can this just occur on an as-needed basis, that is, due to public health emergency or pandemic situations, instead of having two regulatory updates?

According to the commenter, although many were able to adjust to the changes that happened through 2020, a PHE presents very different circumstances compared to adding codes to the classification on an annual or semi-annual basis.

6. How will this affect other regulatory agencies, payment systems and processes?

How will rulemaking be affected, two proposed rules and two final rules?

- MS–DRGs
- APR–DRGs
- Medicaid
- HH Agencies—Patient-Driven Groupings Model
- SNF—Patient Driven Payment Model
- IRF PPS
- Medicare Advantage Plans—HCC
- Commercial HCCs
- OPPS
- Worker's Compensation
- Other state agencies

We also received comments in response to this topic that we consider to be outside the scope of the request for feedback. Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule.

Response: We appreciate the commenters' support and feedback received on what criteria or factors the agencies (Committee) should consider for determining whether to consider a code request for an April 1 or October 1 implementation date, as well, as how it may impact provider's business processes. With respect to commenters' concerns regarding clarity and transparency in the process for how the agencies will communicate timelines and information on which code requests would be considered for April 1 versus an October 1 implementation date, we note that we provide detailed information regarding the ICD–10 Coordination and Maintenance Committee meetings, including detailed timelines in the Agenda and meeting

materials made available on each agency's respective websites. Members of the public may refer to the prior meeting's Agenda and meeting materials for information about upcoming deadlines. Additionally, we discuss information related to the code updates as a result of proposals brought forth to the meetings in the annual IPPS rulemaking process. As noted in the preamble of this final rule, and discussed earlier in this section, the ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 3 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. We note that, on July 26, 2021, the **Federal Register** Notice announcing the September 14–15, 2021 committee meetings was published with the tentative agenda items listed for both diagnosis and procedure code topics. This notice is located at *https://www.federalregister.gov/documents/2021/07/26/2021-15801/national-center-for-health-statistics-nchs-icd-10-coordination-and-maintenance-candm-committee* and specifically indicates for the ICD–10–PCS procedure code topics, which topics are associated with a new technology add-on payment application for FY 2023, as well as, which topic was requested for consideration of an April 1, 2022 implementation date. We note that there were no diagnosis code topics at the time of the development of the **Federal Register** Notice identified as requesting an April 1, 2022 consideration. With respect to communication, in addition to the resources previously discussed, CMS maintains an ICD–10 Maintenance subscriber list to enable members of the public to remain informed of updates related to ICD–10. Instructions on how to join this subscriber list are available on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-Coordination-and-Maintenance-Committee-Meetings*

We believe the combination of these various resources provide the necessary level of transparency regarding information pertaining to the ICD–10 Coordination and Maintenance Committee meeting process.

With regard to concerns about the ability to comment on the MS–DRG assignment of any new codes that may be considered for an April 1 implementation, we note that our current and long-established process includes finalizing procedure codes that have been presented at the March meeting that were unable to be included in the proposed rule. (Diagnosis code proposals discussed at the March meeting are typically not considered for implementation until the following October (18 month delay)). As discussed throughout section II.D. of the preamble of the FY 2022 IPPS/LTCH PPS proposed and final rules, using our established process, we review the predecessor codes MDC, MS–DRG assignment and designation (severity level or O.R. versus Non-O.R.) and consider other relevant factors in the assignment of a new code under the IPPS ICD–10 MS–DRGs. Members of the public have the opportunity to provide feedback on the assignment and designation of the codes if they disagree, which are then considered in the following or future year's rulemaking cycle. As discussed in more detail later in this section of this final rule, as shown in Table 6A.—New Diagnosis Codes associated with this final rule (and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*, there were diagnosis codes discussed at the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee meeting that were not finalized in time to include in the proposed rule. These 12 codes are identified in Table 6A with an asterisk and have been assigned to the most appropriate MDC, MS–DRG, and severity level designation using our established process, for FY 2022. As noted previously, members of the public have the opportunity to provide feedback on the assignment and designation of the codes finalized after the March meeting if they disagree, which are then considered in the following or future year's rulemaking cycle.

The process that was described for the MS–DRG assignment of new procedure codes (and/or diagnosis codes) that could potentially be finalized for an April 1 implementation is the same process that was utilized when the new diagnosis codes for COVID–19 and vaping related disorder were implemented April 1, 2020 and, as discussed earlier in this section, the MS–DRG assignments for the six diagnosis codes that were effective with discharges on and after January 1, 2021. We provided members of the public the opportunity to comment on the MDC, MS–DRG and severity level designation of the six diagnosis codes for FY 2022 consideration in association with the proposed rule, and we did not receive any comments suggesting we consider alternative assignments. To summarize, with respect to an April 1 implementation date, the process as described would consist of the initial assignment for any code finalized for an April 1 implementation to be assigned to the most appropriate MDC, MS–DRG and designation using our established process which would be in effect from April 1 through September 30 of that same calendar and fiscal year, along with the opportunity for members of the public to comment (during the public comment period in association with the proposed rule for the upcoming fiscal year), on any alternate suggestions should they not agree with the initial assignment. As a commenter noted in its comments and discussed earlier in this section, the current GROUPER allows for a comment period prior to implementation in October (of the new GROUPER) and it is important to recognize that revisions may be made from the proposed and final GROUPER especially for new codes.

With respect to commenters' concerns regarding training and education, as outlined in the materials and discussed during the March 9–10, 2021 meetings, if adopted, any codes implemented effective April 1 would be incorporated into the ICD–10–CM Official Guidelines for Coding and Reporting, if applicable, and coding advice would be published in AHA's *Coding Clinic for ICD–10–CM/PCS* publication. We note that the same opportunities, methods and options that are currently utilized to provide education and training on the code updates for the annual October update would also be available for an April 1 implementation date. These include, but are not limited to, workshops, seminars, webinars, podcasts, presentations, electronic communications, announcements via social media, etc.

In response to commenters' concerns regarding the ability of commercial payors to stay up to date on code changes if an April 1 implementation date were to be adopted, we believe that these concerns can be mitigated with limited code updates using a phased in approach. In addition, outreach efforts to better understand why systems are

currently not being updated in a timely manner will help inform where process improvements can begin to ensure compliance. It is not clear to us if payors are not familiar with the HIPAA requirements for use of the current code set.

With respect to concerns about increased costs related to the production and purchase of additional code books or software, we do not believe there is a specific need for publishers to produce new code books for the reasons discussed in the proposed rule. With regard to new software, we were not and have not been made aware of any significant challenges encountered by vendors or programmers during the PHE with the additional GROUPER releases that were made available.

In response to the commenter's process questions, we have provided the following sample timeline from the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee meeting materials and are sharing here to illustrate the process.

Sample Timeline

June 11, 2021

Deadline for requestors: Those members of the public requesting that topics be discussed at the September 14–15, 2021 ICD–10 Coordination and Maintenance Committee Meeting, must have their requests submitted to CMS for procedures and NCHS for diagnoses.

Requestors should indicate if they are submitting their code request for consideration for an April 1, 2022 implementation date, if adopted, or an October 1, 2022 implementation date.

The ICD–10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an April 1, 2022 implementation date or an October 1, 2022 implementation date.

*We are also seeking input on what factors the Committee should consider when determining which requests should be considered for either an April 1, 2022 or October 1, 2022 implementation date.

July 2021

Federal Register notice for the September 14–15, 2021 ICD–10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.

August 2021

FY 2022 Hospital Inpatient Prospective Payment System final rule is issued. This rule will also include links to tables listing all the final codes to be implemented on October 1, 2021.

This rule can be accessed at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

August 2021

Tentative agenda for the Procedure portion of the September 14, 2021 ICD–10 Coordination and Maintenance Committee Meeting will be posted on the CMS web page at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html*.

Tentative agenda for the Diagnosis portion of the September 15, 2021 ICD–10 Coordination and Maintenance Committee Meeting will be posted on the NCHS web page at: *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm*.

If adopted, topics being considered for an April 1 implementation will be identified.

August 9, 2021

On-line registration opens for the September 14–15, 2021 ICD–10 Coordination and Maintenance Committee Meeting at: *https://www.eventbrite.com/e/icd-10-coordination-and-maintenance-committee-meeting-tickets*.

Please note that this meeting will be conducted virtually and registration is not required to attend. However, we are providing the ability to register on-line for those required to provide proof of attendance for continuing education purposes. The on-line registration will be available through September 9, 2021.

September 14–15, 2021

The September 2021 ICD–10 Coordination and Maintenance Committee Meeting will be held fully virtual, with no in-person audience. Those who wish to attend must participate via Zoom Webinar or by dialing in.

September 2021

Recordings and slide presentations of the September 14–15, 2021 ICD–10 Coordination and Maintenance Committee Meeting will be posted on the following web pages:

Diagnosis code portion of the recording and related materials *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm;*

Procedure code portion of the recording and related materials *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html*.

October 1, 2021

New and revised ICD–10–CM and ICD–10–PCS codes go into effect along with MS–DRG changes. Final addendum available on web pages as follows:

Diagnosis addendum *https://www.cdc.gov/nchs/icd/icd10cm.htm*;

Procedure addendum *https://www.cms.gov/Medicare/Coding/ICD10/*.

October 15, 2021

Deadline for receipt of public comments on proposed new codes discussed at the September 14–15, 2021 ICD–10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2022.

November 2021

Any new ICD–10 codes that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2022 will be posted on the following websites: *https://www.cdc.gov/nchs/icd/icd10cm.htm*, *https://www.cms.gov/Medicare/Coding/ICD10/*.

November 15, 2021

Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 14–15, 2021 ICD–10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2022.

December 3, 2021

Deadline for requestors: Those members of the public requesting that topics be discussed at the March XX, 2022 ICD–10 Coordination and Maintenance Committee Meeting, must have their requests submitted to CMS for procedures and NCHS for diagnoses.

Requestors should indicate if they are submitting their code request for consideration for an October 1, 2022 implementation date, or an April 1, 2023 if adopted, implementation date.

The ICD–10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an October 1, 2022 implementation date or an April 1, 2023 implementation date.

January 2022

Federal Register notice for the March X–X, 2022 ICD–10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.

February 1, 2022

ICD–10 MS–DRG Grouper software and related materials posted on CMS web page at: *https://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

February 1, 2022

Any updates to the ICD–10–CM and ICD–10–PCS Coding Guidelines will be posted on the following websites: *https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/.*

February 1, 2022

All ICD–10–CM and ICD–10–PCS code update files (includes April 1 update and full files from prior October 1) will be posted on the following websites: *https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/.*

March 8–9, 2022

ICD–10 Coordination and Maintenance Committee Meeting.

March 2022

Recordings and slide presentations of the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee Meeting will be posted on the following web pages:

Diagnosis code portion of the recording and related materials *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm.*

Procedure code portion of the recording and related materials *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html.*

April 1, 2022

New and revised ICD–10–CM and ICD–10–PCS codes go into effect along with MS–DRG changes.

We note that, as outlined in the sample timeline, by the June 11, 2021 deadline, requestors were encouraged to indicate in their submission of a code request whether they sought consideration for an April 1, 2022 implementation date, if adopted, or an October 1, 2022 implementation date. As discussed earlier in this section, we received one procedure code request for consideration of an April 1, 2022 implementation date for discussion at the September 14–15, 2021 ICD–10 Coordination and Maintenance Committee meeting. There were no diagnosis code requests submitted by that deadline. The process and/or criteria to determine which codes would be implemented in April versus October would include identifying the number of code requests received for consideration of each date, providing the Agenda and meeting materials which indicate the implementation date (April or October) being considered for each topic, using our established process for presenting the code proposal to members of the public participating in the ICD–10 Coordination and Maintenance Committee meeting process, allowing the opportunity for public comments to be submitted following the meeting, agency review of the public comments to determine if there is support for the code proposal, as well as, support for the proposed implementation date.

We also note that enabling code proposals related to diagnosis code topics that are presented in March to be considered for implementation the following April would assist in reducing the current 18-month timeframe that exists to incorporate new diagnosis codes into the classification. We further note that there is additional flexibility with regard to repeat diagnosis code proposals that have been updated and brought back for consideration to be implemented sooner as well. This scenario (repeat proposals) was also suggested by a commenter for the agencies to consider as one of the criteria for consideration of an April 1 implementation date.

With respect to coding guideline updates, any updates to the ICD–10–CM Official Guidelines for Coding and Reporting would depend on the circumstances relating to the new code(s), such that, there may be instances in which no guideline updates are needed and in other instances there may. However, if updates to the guidelines are necessary, the four Cooperating Parties for ICD–10 (AHA, AHIMA, CDC, and CMS) would evaluate and incorporate the necessary information into the appropriate section for all users of the classification accordingly. Coding guideline updates in response to April 1 code updates effective with discharges on and after April 1 are valid beginning on that April 1 date of that fiscal year. These April 1 coding guideline updates would be in addition to the coding guidelines that were effective at the beginning of that same fiscal year. A fiscal year for IPPS purposes begins with discharges on and after October 1 through September 30 of the following year. As displayed in the sample timeline, all materials requiring updates would be made publicly available by February 1 for an April 1 code implementation, including coding guidelines.

Finally, similar to the current process that is involved for users of the classification when incorporating changes associated with the annual October 1 code update, we anticipate that other regulatory agencies would continue to utilize their existing processes to update their payment systems accordingly.

After consideration of the public comments and feedback received, we are adopting an April 1 implementation date, in addition to the annual October 1 update, beginning with April 1, 2022. We note that the intent of this April 1 implementation date is to allow flexibility in the ICD–10 code update process for the reasons previously discussed and based on the feedback received by commenters.

We appreciate the commenters' suggestions on the criteria and/or factors that should be considered by the Committee in determining whether to consider a code request for an April 1 versus an October 1 implementation and note that, as discussed during the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee meeting that we recommend a phased in approach with limited code updates. We acknowledge the concerns that some commenters expressed with respect to potential operational issues and with commercial payers and compliance issues. As noted previously, we intend to work with stakeholders and identify how we can address issues that may arise in this process. We will continue to provide additional information pertaining to the adoption of the April 1 implementation date for new codes in connection with the ICD–10 Coordination and Maintenance Committee meeting process and our annual IPPS rulemaking.

ICD–9–CM addendum and code title information is published on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum*. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*. CMS also sends electronic files containing all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can be found on the CDC website at: *https://www.cdc.gov/nchs/icd/icd10cm.htm.* Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the *Coding Clinic for ICD–10.* The AHA also distributes coding update information to publishers and software vendors.

In the proposed rule we noted that for FY 2021, there are currently 72,621 ICD–10–CM diagnosis codes and 78,136 ICD–10–PCS procedure codes. We also noted that as displayed in Table 6A—New Diagnosis Codes and in Table 6B—New Procedure Codes associated with the proposed rule (and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/*, there were 147 new diagnosis codes and 106 new procedure codes that had been finalized for FY 2022 at the time of the development of the proposed rule. As discussed in section II.D.13 of the preamble of this final rule, we are making available Table 6A—New Diagnosis Codes, Table 6B—New Procedure Codes, Table 6C—Invalid Diagnosis Codes, Table 6D—Invalid Procedure Codes Table 6E—Revised Diagnosis Code Titles, and Table 6F—Revised Procedure Code Titles via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in association with this final rule. As shown in Table 6A—New Diagnosis Codes, there were diagnosis codes discussed at the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee meeting that were not finalized in time to include in the proposed rule. These 12 codes are identified in Table 6A with an asterisk and are as follows.

BILLING CODE 4120–01–P

ICD-10 CM Diagnosis Code	Code Description
U09.9	Post COVID-19 condition, unspecified
Z55.5	Less than a high school diploma
Z58.6	Inadequate drinking-water supply
Z59.00	Homelessness unspecified
Z59.01	Sheltered homelessness
Z59.02	Unsheltered homelessness
Z59.41	Food insecurity
Z59.48	Other specified lack of adequate food
Z59.811	Housing instability, housed, with risk of homelessness
Z59.812	Housing instability, housed, homelessness in past 12 months
Z59.819	Housing instability, housed unspecified
Z59.89	Other problems related to housing and economic circumstances

The addition of these 12 new diagnosis codes to the 147 diagnosis codes that had been finalized at the time of the development of the proposed rule result in a total of 159 (147 + 12 = 159) new diagnosis codes for FY 2022.

Similarly, there were procedure codes discussed at the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee meeting that were not finalized in time to include in the proposed rule and are also identified with an asterisk, as shown in Table 6B—New Procedure Codes. We refer the reader to Table 6B—New Procedure Codes associated with this final rule and available via the internet on the CMS website at:*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* for the detailed list of these additional 85 new procedure codes. The addition of these 85 new procedure codes to the 106 procedure codes that had been finalized at the time of the development of the proposed rule result in a total of 191 (106 + 85 = 191) new procedure codes for FY 2022.

We also note, as reflected in Table 6C—Invalid Diagnosis Codes and in Table 6D—Invalid Procedure Codes, there are a total of 32 diagnosis codes and 107 procedure codes that will become invalid effective October 1, 2021. Based on these code updates, effective October 1, 2021, there are a total of 72,748 ICD–10–CM diagnosis codes and 78,220 ICD–10–PCS procedure codes for FY 2022 as shown in the following table.

FY 2021 ICD-10-CM 72,621 total codes	FY 2021 ICD-10-PCS 78,136 total codes
FY 2022 ICD-10-CM 159 additions	FY 2022 ICD-10-PCS 191 additions
FY 2022 ICD-10-CM 32 deletions	FY 2022 ICD-10-PCS 107 deletions
FY 2022 ICD-10-CM 72,748 total codes	**FY 2022 ICD-10-PCS 78,220 total codes**

As stated previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting. The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. We will continue to provide the October updates in this manner in the IPPS proposed and final rules.

17. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Changes for FY 2022

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25195 through 25198) for FY 2022, we proposed to not add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We proposed to continue to include the existing MS–DRGs currently subject to the policy as displayed in the following table.

MDC	MS-DRG	MS-DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	140	Major Head and Neck Procedures with MCC
03	141	Major Head and Neck Procedures with CC
03	142	Major Head and Neck Procedures without CC/MCC
05	215	Other Heart Assist System Implant
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC
05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC
05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC
05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC

MDC	MS-DRG	MS-DRG Title
05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
05	245	AICD Generator Procedures
05	258	Cardiac Pacemaker Device Replacement with MCC
05	259	Cardiac Pacemaker Device Replacement without MCC
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement And Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement And Supplement Procedures without MCC
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	466	Revision of Hip or Knee Replacement with MCC
08	467	Revision of Hip or Knee Replacement with CC
08	468	Revision of Hip or Knee Replacement without CC/MCC
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	551	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
08	552	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

We did not receive any public comments opposing our proposal to continue to include the existing MS–DRGs currently subject to the policy. Therefore, we are finalizing the list of MS–DRGs in the table included in the proposed rule and in this final rule that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2021.

The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be issued to providers in the form of a Change Request (CR).

18. Out of Scope Public Comments Received

We received public comments on MS–DRG related issues that were outside the scope of the proposals included in the FY 2022 IPPS/LTCH PPS proposed rule.

Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.D.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classifications to submit these comments no later than November 1, 2021 so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

E. Recalibration of the FY 2022 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

In accordance with our final policy in section I.F. of this final rule, for the purposes of establishing the FY 2022 MS–DRG relative weights, we are finalizing our proposal to use the FY 2019 MedPAR claims data, based on claims received by CMS through March 31, 2020, and the March 2020 update of the FY 2018 HCRIS file where we ordinarily would have used the FY 2020 MedPAR claims data, based on claims received by CMS through December 31, 2020, and the December 2020 update of the FY 2019 HCRIS file. We refer the reader to section I.F. of this final rule for further discussion of our analysis of the best available data for purposes of the FY 2022 ratesetting and our related policies.

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2022, we proposed to use two data sources: claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital claims. The FY 2019 MedPAR data used in this final rule include discharges occurring on October 1, 2018, through September 30, 2019, based on claims received by CMS through March 31, 2020, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS).

The FY 2019 MedPAR file used in calculating the relative weights includes data for approximately 9,216,615 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the March 31, 2020 update of the FY 2019 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service.

Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2022 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the FY 2022 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2019 MedPAR claims data, grouped through the ICD–10 version of the FY 2022 GROUPER (Version 39).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. However, as discussed earlier in this section, we proposed to use the March 31, 2020 update of the FY 2018 HCRIS for calculating the FY 2022 cost-based relative weights. Consistent with our historical practice, for this FY 2022 final rule, we are providing the version of the HCRIS from which we calculated these 19 CCRs on the CMS website at: *http://www.cms.gov/Medicare/* Medicare-Fee-for- Service-Payment/AcuteInpatientPPS/index.html. Click on the link on the left side of the screen titled ''FY 2022 IPPS Final Rule Home Page'' or ''Acute Inpatient Files for Download.'' We note that this file is identical to the file used for the FY 2021 IPPS/LTCH PPS final rule. As discussed previously and in the proposed rule, we also made available the FY 2019 HCRIS and the FY 2020 MedPAR file as well as other related information and data files for purposes of public comment on our alternative approach of using the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting.

Comment: A few commenters requested that CMS consider whether an adjustment needs to be made to the normalization factor since the FY 2021 and FY 2022 relative weights were both calculated using the same set of claims data (FY 2019 MedPAR). Specifically, the commenters were concerned about the impact holding real changes in case-mix constant (when calculating the relative weights) might have on accuracy of the FY 2022 relative weights. A commenter stated that ''by using FY 2019 utilization in place of FY 2020 data, the base year weights (FY 2021) will not reflect any changes in case mix that would occur from using FY 2020 compared to FY 2019 utilization. Thus, CMS will be making the payment year weights (FY 2022) budget neutral to a base year that does not reflect any change in real case mix as would normally occur.''

Response: We believe the commenters may have misinterpreted the purpose of the normalization adjustment. The normalization adjustment is the first of two steps performed by CMS to ensure that the recalibration of the relative weights does not increase nor decrease total payments under the IPPS.

The purpose of the normalization factor is to ensure that changes in average case-mix do not impact the final relative weights used for payment purposes. For example, if the average cost of cases grouped to each MS–DRG remained the same from one year to the next, and all that changed was the number of cases grouped to each MS–DRG, the normalization factor would ensure that the final relative weights calculated in each year were the same. This is appropriate since it ensures that when the relative costliness of cases across MS–DRGs is unchanged, the relative weights are unchanged as well. Therefore, if CMS were to somehow

develop a method for introducing some level of real-case mix growth into the FY 2019 claims, the revised normalization factor would produce the same set of final relative weights, since the average cost of claims grouped to each MS–DRG would not have changed.

The result of the normalization adjustment is that the relative weights from both years result in the same average case-mix value when using the same set of utilization. However, the normalization adjustment alone does not completely meet the goal of ensuring that the recalibration of the relative weights does not increase nor decrease total payments under the IPPS. Due to other factors that impact IPPS payments (for example, the wage index), a budget neutrality factor is calculated that ensures the normalized relative weights for the current year result in the same total payments as the normalized relative weights from the previous year. We refer readers to section II.A.4.a of the Addendum to this final rule for a complete discussion on the calculation of the budget neutrality factor for recalibration of MS–DRG relative weights.

To the extent commenters were implying that CMS should simply increase the normalization factor by an estimate of real case mix growth without somehow introducing it into the FY 2019 claims, even putting aside the methodological issues with such an approach, we note that such an increase in the normalization factor would be offset by a larger budget neutrality adjustment.

2. Methodology for Calculation of the Relative Weights

a. General

We calculated the FY 2022 relative weights based on 19 CCRs, as we did for FY 2021. The methodology we proposed to use to calculate the FY 2022 MS–DRG cost-based relative weights based on claims data in the FY 2019 MedPAR file and data from the FY 2018 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the FY 2022 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this final rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2019 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

Section 108 of the Further Consolidated Appropriations Act, 2020 provides that, for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant shall be paid on a reasonable cost basis. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of the reasonable cost basis payment for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 to 58842). For FY 2022 and subsequent years, we proposed to subtract the hematopoietic stem cell acquisition charges from the total charges on each transplant bill that showed hematopoietic stem cell acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.8 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all

claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the BPCI Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 1115A of the Act, is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*. Consistent with our policy for FY 2021, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2022, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted previously, these hospitals are still receiving IPPS payments under section 1886(d) of the Act. Consistent with the FY 2021 IPPS/LTCH PPS final rule, we also proposed to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2018 cost report data, consistent with our FY 2022 ratesetting discussed in section II.A.4 of the Addendum of this final rule.

The 19 cost centers that we used in the relative weight calculation are shown in a supplemental data file, Cost Center HCRIS Lines Supplemental Data File, posted via the internet on the CMS website for this final rule and available at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs. In the proposed rule, we stated that if we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy. However, we did not receive any comments on the groupings in this table, and therefore, we are finalizing the groupings as proposed.

Consistent with historical practice, we account for rare situations of non-monotonicity in a base MS–DRG and its severity levels, where the mean cost in the higher severity level is less than the mean cost in the lower severity level, in determining the relative weights for the different severity levels. If there are initially non-monotonic relative weights in the same base DRG and its severity levels, then we combine the cases that group to the specific non-monotonic MS–DRGs for purposes of relative weight calculations. For example, if there are two non-monotonic MS–DRGs, combining the cases across those two MS–DRGs results in the same relative weight for both MS–DRGs. The relative weight calculated using the combined cases for those severity levels is monotonic, effectively removing any non-monotonicity with the base DRG and its severity levels. For this FY 2022 final rule, this calculation was applied to address non-monotonicity for cases that grouped to MS–DRG 504 and MS–DRG 505. We note that cases were also combined in calculating the relative weights for these two MS–DRGs for FY 2021. In the supplemental file titled AOR/BOR File, we include statistics for the affected MS–DRGs both separately and with cases combined.

In the proposed rule, we invited public comments on our proposals related to recalibration of the FY 2022 relative weights and the changes in relative weights from FY 2021. We did not receive any public comments on these proposals. Therefore, we are finalizing our proposed policies with respect to the recalibration of the FY 2022 relative weights.

b. Relative Weight Calculation for MS–DRG 018

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58599 through 58600), we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. We refer the reader to section II.D.2. of this final rule for discussion of the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies that are finalizing for assignment to MS–DRG 018 for FY 2022.

In the FY 2021 IPPS/LTCH PPS final rule, we finalized our proposals to modify our existing relative weight methodology to ensure that the relative weight for new MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell therapy outside of a clinical trial, while still accounting for the clinical

trial cases in the overall average cost for all MS–DRGs, with additional refinements in response to comments. For cases that group to MS–DRG 018, we finalized to not include claims determined to be clinical trial claims that group to new MS–DRG 018 when calculating the average cost for new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). We also finalized our proposal to calculate an adjustment to account for the CAR T-cell therapy cases determined to be clinical trial cases, as described in the FY 2021 IPPS/LTCH PPS final rule, with the additional refinement of including revenue center 891 in our calculation of standardized drug charges for MS–DRG 018. Applying this finalized methodology, based on the March 2020 update of the FY 2019 MedPAR file for the FY 2021 IPPS/LTCH PPS final rule, we estimated that the average costs of CAR T-cell therapy cases determined to be clinical trial cases ($46,062) were 17 percent of the average costs of CAR T cell therapy cases determined to be non-clinical trial cases ($276,042), and therefore, in calculating the national average cost per case for purposes of the FY 2021 IPPS/LTCH PPS final rule, each case identified as a clinical trial case was adjusted by 0.17. We also noted that we were applying this adjustor for cases determined to be CAR T-cell therapy clinical trial cases for purposes of budget neutrality and outlier simulations. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for complete discussion of our finalized modifications to the relative weight calculation for MS–DRG 018.

Since we proposed to use the same FY 2019 MedPAR claims data for FY 2022 ratesetting that we did for the FY 2021 final rule, we also proposed to continue to use the same process to identify clinical trial claims in the FY 2019 MedPAR for purposes of calculating the FY 2022 relative weights. We continue to use the proxy of standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA, which are the two CAR T-cell biological products in the MedPAR data used for the FY 2021 final rule and this final rule. Using the same methodology from the FY 2021 IPPS/LTCH PPS final rule, we proposed to apply an adjustment to account for the CAR T cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs:

Step 1—Calculate the average cost for cases to be assigned to new MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.

Step 2—Calculate the average cost for cases to be assigned to new MS–DRG 018 that do not contain ICD–10–CM diagnosis code Z00.6 or standardized drug charges of at least $373,000.

Step 3—Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.

Step 4—Apply the adjustor calculated in step 3 to the cases identified in step 1 as clinical trial cases, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Additionally, we are continuing our finalized methodology for calculating this payment adjustment, such that: (a) When the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases. However, we continue to believe to the best of our knowledge there are no claims in the historical data (FY 2019 MedPAR) used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000. Consistent with our proposal to use the FY 2019 data for the FY 2022 ratesetting, we also proposed to calculate this adjustor based on the March 2020 update of the FY 2019 MedPAR file for purposes of establishing the FY 2022 relative weights. Accordingly, as we did for FY 2021, we proposed to adjust the transfer-adjusted case count for MS–DRG 018 by applying the proposed adjustor of 17 percent to the applicable clinical trial cases, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of the proposed rule, each case identified as a clinical trial case was adjusted by 17 percent. As we did for FY 2021, we proposed to apply this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations.

As discussed in section I.F. of this final rule, we also solicited comments on an alternative approach of using the same FY 2020 data that we would ordinarily use for purposes of the FY 2022 rulemaking, which we stated we may consider finalizing for FY 2022 based on consideration of comments received. We noted that using the methodology as finalized in the FY 2021 IPPS/LTCH PPS final rule, we calculated an adjustor of 0.25 based on this alternative approach of using the FY 2020 MedPAR file.

Comment: The majority of commenters supported CMS' proposal to use the same ratesetting methodology for MS–DRG 018 in FY 2022 as it did in FY 2021. Commenters stated that the inclusion of cases without product acquisition costs would compromise the relative weight calculation. The majority of commenters also supported CMS' proposal to apply an adjustor to expanded access or clinical trial cases. While the majority of commenters generally supported CMS' proposed adjustor of 0.17, calculated based on the FY 2019 MedPAR data, some commenters requested that we use the calculated adjustment of 0.25 from the FY 2020 MedPAR data. Some commenters also requested that CMS raise the $373,000 threshold or otherwise modify the methodology so that more cases would be classified into the expanded access or clinical trial case cohort.

Response: We appreciate the support and feedback on our proposal to use the same ratesetting methodology for MS–DRG 018 in FY 2022 as we did in FY 2021, including the application of an adjustor for expanded access or clinical trial cases.

In response to commenters who requested that CMS raise the $373,000 threshold or otherwise modify the methodology so that more cases would be classified into the expanded access or clinical trial case cohort, as noted earlier, we are using the FY 2019 MedPAR to approximate the relative resource use for each MS–DRG. This is the same data source that was used to approximate the relative resource use

for determining the FY 2021 MS–DRG relative weights. As we discussed in the FY 2021 IPPS/LTCH PPS final rule, we believe that given this data source, our methodology to divide cases into these cohorts provides reasonable estimates on average of the costs of the cases in these cohorts. (85 FR 58599) As we are continuing to use the same data source that was used for purposes of the FY 2021 MS–DRG relative weights and the calculation of the adjustor to the relative weight for MS–DRG 018, it continues to be reasonable that in that data source, hospitals would not generally have charges of greater than $373,000 in the absence of incurring the cost of the CAR T-cell drug. As previously noted, we used the proxy of standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA, which are the two CAR T-cell biological products in the MedPAR data used for the FY 2021 final rule and this final rule.

In response to commenters who requested that we use the calculated adjustment of 0.25, we disagree that we should use the adjustment of 0.25 calculated from the FY 2020 MedPAR data instead of the 0.17 adjustment calculated from the FY 2019 MedPAR data. Given that under the IPPS the relative weight assigned to each MS–DRG reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other MS–DRGs, it would be inappropriate to use the FY 2019 MedPAR to approximate the relative resource use for each MS–DRG, including the majority of MS–DRG 018 cases, but then a different data source (that is, the FY 2020 MedPAR) to determine the relative resources required for MS–DRG 018 cases that are expanded access or clinical trial cases to calculate the adjustor.

Comment: Several commenters stated that the MS–DRG relative weight for MS–DRG 018 does not result in payment that fully covers the hospital resource costs, including the cost of the drug. Some commenters indicated that CMS should make structural changes to the IPPS, such as incorporating the Average Sales Price of the CAR T-cell drug into the IPPS relative weight calculation rather than use our usual methodology for determining the MS–DRG relative weight, or we should base the Medicare payment itself on the Average Sales Price of the CAR T-cell drug. For example, some commenters stated that the price of the CAR T-cell drug is expected to increase soon and the IPPS payment does not reflect price increases in a timely manner.

Response: With regard to the comment that the MS–DRG relative weight for MS–DRG 018 does not result in payment that fully covers the hospital resource costs, we note that the IPPS is a prospective payment system and not a cost reimbursement system. The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund. Cost reimbursement is not the optimal means of achieving these objectives. As indicated earlier, under the IPPS the relative weight assigned to each MS–DRG reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other MS–DRGs. For the reasons described earlier, CMS is using the FY 2019 MedPAR data to determine the MS–DRG relative weights for FY 2022, including the relative weight for MS–DRG 018.

We appreciate the commenters' recommendations for structural changes to the IPPS, but as we stated in response to similar comments in the FY 2021 rulemaking, we believe that is premature to make structural changes to the IPPS at this time to pay for CAR T-cell therapies. (85 FR 58453). As we gain more experience paying for these therapies under the IPPS, we may consider these comments to inform future rulemaking.

Comment: Some commenters requested clarifications or raised concerns regarding hospital charging practices for CAR T-cell therapies, including the ability of hospitals to set charges for CAR T-cell drugs consistent with their CCRs. Some commenters requested that CMS establish a dedicated CAR T-cell cost center, which they stated would allow hospitals to set charges appropriate for CAR T-cell therapy.

Response: As we noted in response to similar comments in the FY 2021 IPPS final rule, there is nothing that precludes hospitals from setting their drug charges consistent with their CCRs (85 FR 58453). We also highlight our statements in prior rulemaking regarding our existing administrative mechanisms for hospitals to voluntarily establish lower charges (85 FR 58874). Specifically, if a hospital is planning on voluntarily lowering its charges, it can request a CCR change in accordance with 42 CFR 412.84(i)(1) and as also discussed in prior rulemaking (84 FR 42630). For example, a hospital could use these existing administrative mechanisms to request a CCR closer to 1.0. We appreciate the commenters' requests regarding the creation of new cost centers and may consider this request in future rulemaking. However, we believe that such a step is not necessary at this time given that hospitals are not precluded from setting their charges consistent with their CCRs and the existing administrative mechanisms for hospitals to request CCR changes consistent with lower charges.

We also note that some commenters requested additional clarifications regarding billing instructions for CAR T-cell therapies, for example, relating to the use of hospital charges in apportioning costs under section 2203 of the Provider Reimbursement Manual. We do not believe changes to billing guidance are needed at this time but will take these comments into consideration when developing policies and program requirements for future years for CAR T-cell therapy policy.

After consideration of the public comments received, we are finalizing our proposal regarding the calculation of the relative weight for MS–DRG 018.

3. Development of National Average CCRs

Consistent with our final policy to use the FY 2019 data for the FY 2022 ratesetting, as discussed earlier in this section, we are finalizing our proposal to continue to use the national average CCRs that were calculated for the FY 2021 final rule using that same data. Specifically, we calculated these national average CCRs as follows:

Using the FY 2018 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the

cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight. The FY 2022 cost-based relative weights were then normalized by an adjustment factor of 1.820829 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 19 national average CCRs for FY 2022 are as follows:

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Group	CCR
Routine Days	0.422
Intensive Days	0.345
Drugs	0.187
Supplies & Equipment	0.297
Implantable Devices	0.293
Inhalation Therapy	0.147
Therapy Services	0.288
Anesthesia	0.071
Labor & Delivery	0.359
Operating Room	0.167
Cardiology	0.094
Cardiac Catheterization	0.10
Laboratory	0.106
Radiology	0.136
MRIs	0.07
CT Scans	0.034
Emergency Room	0.147
Blood and Blood Products	0.27
Other Services	0.344

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system. When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We used that same case threshold in recalibrating the MS–DRG relative weights for FY 2022. Using data from the FY 2019 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. For FY 2022, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we proposed to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2021 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2021 to FY 2022. The crosswalk table is as follows:

Low-Volume MS-DRG	MS-DRG Title	Crosswalk to MS-DRG
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	Final FY 2021relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

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We did not receive any public comments on our proposals and we are finalizing our proposals without modification.

F. Add-On Payments for New Services and Technologies for FY 2022

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. We note that, beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs. The regulations at 42 CFR 412.87 implement these provisions and 42 CFR 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d). We note that section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. Therefore, as discussed in prior rulemaking (72 FR 47307 through 47308), we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs. In this rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For a complete discussion of the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

a. New Technology Add-On Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS–DRGs, based on available data, to reflect the cost of the technology. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective

payment rate, we evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs). The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2022 are presented in a data file that is available, along with the other data files associated with the FY 2021 IPPS/LTCH PPS final rule and correction notice, on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

We note that, under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58603 through 58605), beginning with FY 2022, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2023 were presented in a data file that is available on the CMS website, along with the other data files associated with the FY 2022 proposed rule, by clicking on the FY 2022 IPPS Proposed Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We note, for the reasons discussed in section I.F. of the preamble of the proposed rule and this final rule, we proposed to use the FY 2019 MedPAR claims data where we ordinarily would have used the FY 2020 MedPAR claims data for purposes of proposed FY 2022 ratesetting. We refer the reader to section I.F. of the preamble of this final rule for further discussion of our analysis of the best available data for FY 2022 ratesetting and our related proposals, as well as our finalized policy to use the FY 2019 MedPAR claims data where we ordinarily would have used the FY 2020 MedPAR claims data for purposes of FY 2022 ratesetting. For the FY 2023 proposed threshold values, consistent with our proposal, we proposed to use FY 2019 claims data to evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the proposed FY 2022 standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge (using FY 2019 claims data) for all cases in the MS–DRG (using FY 2019 claims data) to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs), rather than the FY 2020 data we would otherwise use. As discussed in section I.F. of the preamble of this final rule, we also considered, as an alternative to our proposal, the use of the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting. We stated that if we were to finalize this alternative approach for FY 2022, we would use the FY 2020 claims data for purposes of the final thresholds for applications for new technology add-on payments for FY 2023 in the FY 2022 IPPS/LTCH PPS final rule. We made available the threshold values calculated using the FY 2020 claims data at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

As discussed in section I.F. of the preamble of this final rule, we are finalizing our proposal to use the FY 2019 MedPAR claims data where we ordinarily would have used the FY 2020 MedPAR claims data for purposes of FY 2022 ratesetting. Accordingly, consistent with this final policy, we are finalizing to use FY 2019 claims data to set the thresholds for applications for new technology add-on payments for FY 2023 in this final rule. The finalized thresholds for applications for new technology add-on payments for FY 2023 are presented in a data file that is available on the CMS website, along with the other data files associated with this FY 2022 final rule, by clicking on the FY 2022 IPPS Final Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001 final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

(3) Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292), we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical

service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

• Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

• The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

• The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS final rule (67 FR 50015), that although we are affiliated with the FDA and we do not question the FDA's regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not rely upon FDA criteria in our determination of what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. Our criteria do not depend on the standard of safety and efficacy on which the FDA relies but on a demonstration of substantial clinical improvement in the Medicare population (particularly patients over age 65).

c. Alternative Inpatient New Technology Add-On Payment Pathway

Beginning with applications for FY 2021 new technology add-on payments, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. Additionally, under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by the FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by the FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for a complete discussion on this policy. We note that a technology is not required to have the specified FDA designation at the time the new technology add-on payment application is submitted. CMS will review the application based on the information provided by the applicant under the alternative pathway specified by the applicant. However, to receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable.

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of FDA's Breakthrough Devices Program and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. This policy is codified at § 412.87(c). Under this alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) and that is part of FDA's Breakthrough Devices Program will need to meet the cost criterion under § 412.87(b)(3), and will be considered new as reflected in § 412.87(c)(2). We note, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736), we clarified our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736) for a complete discussion regarding this clarification.

(2) Alternative Pathway for Certain Antimicrobial Products

For applications received for new technology add-on payments for certain antimicrobial products, beginning with FY 2021, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, and, beginning with FY 2022, if a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway, it will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. We codified this policy at § 412.87(d). Under this alternative pathway for QIDPs and LPADs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP or approved under the LPAD pathway will need to meet the cost criterion under § 412.87(b)(3), and will be considered new as reflected in § 412.87(d)(2).

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for a complete discussion on this policy. We note, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737

through 58739), we clarified that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation. We also finalized our policy to expand our alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway and used for the indication approved under the LPAD pathway.

d. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. As noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (72 FR 47307 through 47308).

For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying operating cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), CMS made an add-on payment equal to the lesser of: (1) 50 Percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 Percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 Percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product approved under FDA's LPAD pathway, beginning with discharges on or after October 1, 2020, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 Percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for certain antimicrobial products (QIDPs and LPADs)) of the estimated costs of the new technology or medical service.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for complete discussion on the increase in the new technology add on payment beginning with discharges on or after October 1, 2019.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

e. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We specified that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS final rule, to more precisely describe the various types of FDA approvals, clearances and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to the regulation to indicate that new technologies must receive FDA marketing authorization (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request, or approval of a New Drug Application (NDA)) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Consistent with our longstanding policy, we consider FDA marketing authorization as representing that a product has received FDA approval or clearance when considering eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

Additionally, in the FY 2021 IPPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

f. Council on Technology and Innovation (CTI)

The Council on Technology and Innovation at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes

for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local Medicare Administrative Contractors (MACs) (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS website, in a user friendly format. This guide was published in 2010 and is available on the CMS website at: *https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf*.

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invited any product developers or manufacturers of new medical services or technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov*.

g. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2023 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously described), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2023, the CMS website also will post the tracking forms completed by each applicant. We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA and approved under OMB control number 0938–1347.

As discussed previously, in the FY 2020 IPPS/LTCH PPS final rule, we adopted an alternative inpatient new technology add-on payment pathway for certain transformative new devices and for Qualified Infectious Disease Products, as set forth in the regulations at § 412.87(c) and (d). The change in burden associated with these changes to the new technology add-on payment application process were discussed in a revision of the information collection requirement (ICR) request currently approved under OMB control number 0938–1347. In accordance with the implementing regulations of the PRA, we detailed the revisions of the ICR and published the required 60-day notice on August 15, 2019 (84 FR 41723) and 30-day notice on December 17, 2019 (84 FR 68936) to solicit public comments.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2022 prior to publication of the FY 2022 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on October 16, 2020 (85 FR 65815), and held a virtual town hall meeting on December 15 and 16, 2020. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2022 new medical service and technology add on payment applications before the publication of the FY 2022 IPPS/LTCH PPS proposed rule.

Approximately 330 individuals registered to attend the 2-day virtual town hall meeting. We posted the recordings of the 2-day virtual town hall on the CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*. We considered each applicant's presentation made at the town hall meeting, as well as written comments received by the December 28, 2020 deadline, in our evaluation of the new technology add-on payment applications for FY 2022 in the development of the FY 2022 IPPS/LTCH PPS proposed rule.

In response to the published notice and the December 15–16, 2020 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2022 new technology add on payments. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (85 FR 65815 through 65817), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion with regard to pending new technology add-on payment applications for FY 2022. Therefore, we did not summarize the written comments in the proposed rule that were unrelated to the substantial clinical improvement criterion. In section II.H.5. of the preamble of the proposed rule, we summarized comments regarding individual applications, or, if applicable, indicated that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *https://www.cms.gov/medicare/icd-10/2021-icd-10-pcs*, including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. FY 2022 Status of Technologies Approved for FY 2021 New Technology Add-On Payments

In this section of the final rule, we discuss the proposed FY 2022 status of 23 technologies approved for FY 2021 new technology add-on payments, and our finalized policies, as set forth in the tables that follow. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. We refer the reader to section II.F.6.b.(1). of the preamble of this final rule for discussion of CONTEPO, which we conditionally approved for FY 2021 new technology add-on payments under the alternative pathway for certain antimicrobial products, subject to the technology receiving FDA marketing authorization by July 1, 2021. We note that CONTEPO did not receive FDA marketing authorization by July 1, 2021. As discussed in section II.F.6.b.(1). of the preamble of this final rule, because the applicant for CONTEPO submitted a new application for FY 2022, we are conditionally approving CONTEPO for FY 2022 new technology add-on payments under the alternative pathway for certain antimicrobial products, subject to the technology receiving FDA marketing authorization by July 1, 2022.

a. Continuation of New Technology Add-On Payments for FY 2022 for Technologies Still Considered to be New

In the table in section II.F (Proposed Add-On Payments for New Services and Technologies for FY 2022) of the proposed rule (86 FR 25208 through 25211), we presented our proposals to continue the new technology add-on payment for FY 2022 for those technologies that were approved for the new technology add-on payment for FY 2021 and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2022.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

In the proposed rule, we provided a table listing the technologies for which we proposed to continue making new technology add-on payments for FY 2022 because they would still be considered new for purposes of new technology add-on payments (86 FR 25209). This table also presented the newness start date, new technology add-on payment start date, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments. We referred readers to the cited final rules in the table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We summarize in this section of this final rule the comments we received regarding our proposal to continue making new technology add-on payments for FY 2022 for the technologies listed in the table in the proposed rule because they would still be considered new for purposes of new technology add-on payments.

Comment: Commenters overwhelmingly supported our proposed continuation of new technology add-on payments for FY 2022 for those technologies that were approved for the new technology add-on payment for FY 2021 and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2022.

Response: We appreciate the commenters' support.

Comment: A commenter, the applicant for Jakafi®, requested the maximum new technology add-on payment amount for Jakafi® be updated from $4,096.21 to $6,885.20 to reflect the updated Wholesale Acquisition Cost (WAC) for 60 Jakafi tablets using a 14-day anticipated duration.

Response: We appreciate the updated cost information from the applicant. Jakafi's current WAC is $14,754.00 per 60 tablets. The maximum NTAP, using

the WAC for 60 Jakafi tablets, determining the per tablet amount, multiplying that figure by two (Jakafi taken twice daily), and using a 14 day anticipated duration, the average cost per case would change to $4,475.38 ($14,754.00/60 * 2 * 14) * .65. Based on this updated information, the maximum new technology add-on payment for Jakafi® for FY 2022 would be $4,475.38, as reflected in the table in this section.

Comment: The manufacturer for Azedra® stated that the newness period for Azedra® should start with the first sale which would be June 6, 2019 instead of July 30, 2018. Based on this date, the commenter stated that the three-year anniversary of that date would be June 6, 2022, which would be in the latter half of FY 2022. The applicant noted that under longstanding CMS practice and policy, a technology generally receives an additional year of new technology add-on payments if the third anniversary of the product's market entry date occurs in the latter half of the relevant fiscal year.

The commenter added if CMS does not agree that the date of the first sale of Azedra® should be used as the date when the product became available on the market, then it believes that an appropriate alternative for the start date of Azedra's® market availability is May 21, 2019, as this was the date that the first doses of the product were delivered to be used as dosimetry doses for two patients who subsequently received their first therapeutic doses of Azedra® in June 2019 and July 2019, respectively. More specifically, the commenter explained that its records indicate that, prior to May 2019, it received but was not able to fulfill attempted orders for Azedra® due to lack of product availability. Accordingly, the records reflect that the first doses of Azedra® became available on the market in May 2019. The commenter confirmed, however, that the first orders of Azedra® that were fulfilled in May 2019 were used for dosimetry doses for two patients who, as noted, subsequently received their first therapeutic doses of Azedra® in June 2019 and July 2019, respectively. The first therapeutic doses of Azedra® were not available or possible to calculate until after the results of the dosimetry dose were obtained.

Commenters also stated that CMS should finalize its proposal to continue Azedra's® new technology add-on payments for FY 2022 even if CMS does not finalize its proposal to use the FY 2019 MedPAR claims data for the FY 2022 IPPS ratesetting. Commenters emphasized that the condition Azedra® is indicated to treat is exceedingly rare and as a result, use of Azedra® is quite infrequent. A commenter believes that the realities with respect to the nature of Azedra®, the ultra-orphan condition it treats, and the infrequency of its use provide further support for the continuation of new technology add-on payments for Azedra® for FY 2022, particularly in light of the unique circumstances in FY 2020 and FY 2021 related to utilization of hospital services because of the COVID–19 pandemic and PHE. The commenter believes another year of new technology add-on payments for Azedra® will be critical for purposes of additional data collection and further opportunity for relevant MS–DRGs to adjust to the availability of this innovative, yet very infrequently used, therapy.

Response: We thank the commenter for their comments and we agree that the newness date for Azedra® should begin on May 21, 2019. We believe Azedra® was available on the market beginning May 21, 2019 rather than July 30, 2018 as May 21, 2019 was the date that the first doses of the product were delivered to be used. Based on the information available at the time, we indicated in the proposed rule that the newness date for Azedra® started on July 30, 2018 and we included Azedra® in our table of technologies that we proposed a one-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued. Based on the comment from the manufacturer, Azedra® is still new for FY 2022 and is eligible to continue new technology add-on payments for FY 2022 since the 3-year anniversary date of the entry of Azedra® onto the U.S. market (May 21, 2022) will occur in the second half of FY 2022. Therefore, we are including Azedra® in the table below for technologies that were approved for the new technology add-on payment for FY 2021 and that would still be considered ''new'' for purposes of new technology add-on payments for FY 2022. Finally, with regard to the comment about the FY 2020 MedPAR data, we did not finalize use of the FY 2020 MedPAR data for the FY 2022 ratesetting and Azedra® is still new for FY 2022. Also, in the FY 2006 IPPS final rule (70 FR 47349), we state that case volume is not a relevant consideration for making the determination as to whether a product is new. We refer the reader to the FY 2006 IPPS final rule for a complete discussion on this.

After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for FY 2022 for the technologies that were approved for the new technology add-on payment for FY 2021 and that would still be considered ''new'' for purposes of new technology add-on payments for FY 2022, as listed in the proposed rule and in the following table in this section of this final rule. We note, the table below is the same as it was in the proposed rule, but the table in this final rule includes Azedra® and the updated cost information for Jakafi®, as discussed previously. The following table also presents the newness start date, new technology add-on payment start date, relevant final rule citations from prior fiscal years, maximum add-on payment amount, and coding assignments. We refer readers to the cited final rules in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

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Continuation of Technologies Approved for FY 2021 New Technology Add-on Payments Still Considered New for FY 2022							
	Technology	**FDA/Newness Start Date**	**NTAP Start Date**	**NTAP Status for FY 2022**	**Previous Final Rule Citations**	**Maximum NTAP Amount for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
1	*Balversa™*	*04/12/2019*	*10/01/2019*	*Continue because 3-year anniversary date (4/12/2022) will occur in the second half of FY 2022*	(84 FR 42237 through 42242) and (85 FR 58616)	$3,563.23	XW0DXL5
2	*Jakafi®*	*05/24/2019*	*10/01/2019*	*Continue because 3-year anniversary date (5/24/2022) will occur in the second half of FY 2022*	(84 FR 42265 through 42273) and (85 FR 58617 through 58618)	$4,475.38	XW0DXT5
3	*BAROSTIM NEO™ System*	*08/16/2019*	*10/01/2020*	*Continue because 3-year anniversary date (8/16/2022) will occur in the second half of FY 2022*	(85 FR 58716 through 58717)	$22,750	0JH60MZ in combination with 03HK0MZ or 03HL0MZ
4	*FETROJA® (Cefiderocol)*	*11/19/2019 commercially available in US 2/24/2020*	*10/01/2020*	*Continue because 3-year anniversary date (2/24/2023) will occur after FY 2022*	(85 FR 58721 through 58723)	$7,919.86	XW03366 or XW04366
5	*Optimizer® System*	*10/23/2019*	*10/01/2020*	*Continue because 3-year anniversary date (10/23/2022) will occur after FY 2022*	(85 FR 58720 through 58721)	$14,950	0JH60AZ, 0JH63AZ, 0JH80AZ or 0JH83AZ
6	*RECARBRIO™*	*07/16/2019 commercially available in US 1/6/2020*	*10/01/2020*	*Continue because 3-year anniversary date (1/6/2023) will occur after FY 2022*	(85 FR 58727 through 58729)	$3,532.78	XW033U5 or XW043U5

Continuation of Technologies Approved for FY 2021 New Technology Add-on Payments Still Considered New for FY 2022							
	Technology	FDA/Newness Start Date	NTAP Start Date	NTAP Status for FY 2022	Previous Final Rule Citations	Maximum NTAP Amount for FY 2022	Coding Used to Identify Cases Eligible for NTAP
7	*Soliris®*	*06/27/2019*	*10/01/2020*	*Continue because 3-year anniversary date (6/27/2022) will occur in second half of FY 2022*	(85 FR 58684 through 58689)	$21,199.75	XW033C6 and XW043C6
8	*XENLETA™*	*08/19/2019 commercially available in US 9/10/2019*	*10/01/2020*	*Continue because 3-year anniversary date (9/10/2022) will occur in the second half of FY 2022*	(85 FR 58729 through 58732)	$1,275.75	XW03366, XW04366 or XW0DX66
9	*ZERBAXA®*	*06/03/2019*	*10/01/2020*	*Continue because 3-year anniversary date (6/3/2022) will occur in the second half of FY 2022*	(85 FR 58732 through 58733)	$1,836.98	XW03396 or XW04396
10	*Azedra®*	*05/21/2019*	*10/01/2019*	*Continue because 3-year anniversary date (5/21/2022) will occur in the second half of FY 2022*	(84 FR 42194 through 42201) and (85 FR 58615 through 58733)	$98,150	XW033S5 and XW043S5

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b. Extension of New Technology Add-On Payments

Section 1886(d)(5)(K)(ii)(II) of the Act provides for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. As explained in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. Generally, we use FDA, marketing authorization (for example, approval of an NDA) as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRGs. The costs of the new medical service or technology, once paid for by Medicare for this 2-year to 3-year period, are accounted for in the MedPAR data that are used to recalibrate the DRG weights on an annual basis. Therefore, we limit the add-on payment window for those technologies that have passed this 2-to 3-year timeframe.

As discussed in the FY 2006 IPPS final rule (70 FR 47349) and subsequent years, we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Therefore, if a product is more than 2 to 3 years old, we have historically considered its costs to be included in the MS–DRG relative weights whether its use in the Medicare

population has been frequent or infrequent.

However, in light of the unique circumstances for FY 2022 ratesetting, for which we proposed to use the FY 2019 MedPAR claims data where we ordinarily would have used the FY 2020 MedPAR claims data for purposes of developing the FY 2022 relative weights, for the reasons discussed in section I.F. of the preamble of the proposed rule and this final rule, we stated in the proposed rule that we believe it may be appropriate to make a one-time exception to this long-standing policy for all technologies approved for new technology add-on payments for FY 2021, but for which the add-on payments would otherwise be discontinued beginning in FY 2022 because the technologies would no longer be considered new.

As discussed in section I.F. of the preamble of the proposed rule and this final rule, ordinarily, the best available MedPAR data for ratesetting would be the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. For FY 2022 ratesetting, under ordinary circumstances, the best available data would be the FY 2020 MedPAR file. As discussed in section I.F. of the preamble of the proposed rule and this final rule, the FY 2020 MedPAR claims file contains data significantly impacted by the COVID–19 PHE, primarily in that the utilization of inpatient services was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. Accordingly, we questioned whether the FY 2020 MedPAR claims file is the best available data to use for the FY 2022 ratesetting.

In our discussion in section I.F. of the preamble of the proposed rule and this final rule, we highlighted two factors we considered in assessing which data sources would represent the best available data to use in the FY 2022 ratesetting. The first factor is whether the FY 2019 data, which is from before the COVID–19 PHE, or the FY 2020 data, which includes the COVID–19 PHE time period, is a better overall approximation of the FY 2022 inpatient experience. After analyzing this issue, for the reasons discussed in section I.F. of the preamble of the proposed rule and this final rule, we stated in the proposed rule that we believe for purposes of the proposed rule that FY 2019 data are generally a better overall approximation of FY 2022. The second factor is to what extent the decision to use the FY 2019 or FY 2020 data differentially impacts the FY 2022 IPPS ratesetting. As discussed more fully in section I.F. of the preamble of the proposed rule and this final rule, after analyzing this issue, we determined that the decision does differentially impact the overall FY 2022 IPPS ratesetting. For example, we determined that the effect of the FY 2022 MS–DRG relative weights is more limited if the FY 2019-based weights are used rather than the FY 2020-based weights, should the FY 2022 inpatient experience not match the assumption used to calculate the MS–DRG relative weights.

Based on our analyses, we proposed to use FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE. We stated in the proposed rule that because we believe the FY 2020 MedPAR claims data is significantly impacted by the COVID–19 PHE, we were proposing to use the FY 2019 MedPAR claims data for purposes where we ordinarily would have used the FY 2020 MedPAR claims data, including for purposes of developing the FY 2022 relative weights. We referred the reader to section I.F. of the preamble of the proposed rule for a further discussion on our analysis of the best available data for FY 2022 ratesetting. We refer the reader to section I.F. of the preamble of this final rule for a discussion of our finalized policy on the use the FY 2019 data for the FY 2022 ratesetting.

As discussed previously, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. We stated in the proposed rule that because we were proposing to use FY 2019 MedPAR data instead of FY 2020 MedPAR data for the FY 2022 IPPS ratesetting, the costs for a new technology for which the 3-year anniversary date of the product's entry onto the U.S. market occurs prior to the latter half of the upcoming fiscal year (FY 2022) may not be fully reflected in the MedPAR data used to recalibrate the MS–DRG relative weights for FY 2022. Therefore, in light of our proposal to use FY 2019 data instead of FY 2020 data to develop the FY 2022 relative weights, we stated that we believe it would be appropriate to allow for a 1-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022. Accordingly, we proposed to use our authority under section 1886(d)(5)(I) of the Act to provide for a 1-year extension of new technology add-on payments for FY 2022 for those technologies listed in the table presented in section II.F of the proposed rule (86 FR 25213). We noted that if we were to finalize our alternative approach of using the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting, including development of the FY 2022 relative weights, as discussed in section I.F. of the preamble of the proposed rule and this final rule, we would also finalize to discontinue the new technology add-on payments for these expiring technologies beginning in FY 2022, consistent with our historic policies.

We noted that the table in the proposed rule also presented the newness start date, new technology add-on payment start date, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments for these technologies. We referred readers to the final rules cited in the table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We invited public comment on our proposal to use our authority under section 1886(d)(5)(I) of the Act to provide for a 1-year extension of new technology add-on payments for FY 2022 for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022.

We also noted with regard to ContaCT, which is a technology sold on a subscription basis, we continued to welcome comments from the public as to the appropriate method to determine a cost per case for technologies sold on a subscription basis, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

We summarize in this section the comments we received regarding our proposal to provide for a 1-year extension of new technology add-on payments for FY 2022 for those technologies listed in the table in the proposed rule for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022.

Comment: Commenters overwhelmingly supported our proposal to use FY 2019 data instead of FY 2020

data to develop the FY 2022 relative weights and allow for a one-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022.

Response: We appreciate the commenters' support.

Comment: We received a public comment from the applicants for NUZYRA® and IMFINZI® supporting our proposal to extend new technology add-on payments and requesting an additional extension for add-on payments through FY 2023. The applicant for IMFINZI® stated that CMS should evaluate the impact of the COVID 19 PHE on FY 2021 MedPAR claims data to determine if FY 2019 data should also be utilized in lieu of FY 2021 data for FY 2023 rate-setting. The applicant for NUZYRA® asserted that this extension would align with CMS' analysis and acknowledgement in the proposed rule that claims data from FY 2020 may not be appropriate to use in determining prospective hospital payment in the future due to the extenuating circumstances surrounding the COVID public health crisis.

Response: We thank the commenters for their comments. As noted, we proposed a one-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022 because of our proposal to use FY 2019 data instead of FY 2020 data to develop the FY 2022 relative weights. We refer the reader to the discussion in section I.F. of the preamble of this final rule for a discussion of our finalized policy on the use the FY 2019 data for the FY 2022 ratesetting.

Comment: A commenter stated that effective May 5, 2021, the new Wholesale Acquisition Cost (WAC) for ELZONRIS™ is $28,065.44 and requested that CMS update the new technology add-on payment amount accordingly.

Response: We appreciate the updated information from the applicant. Based on this updated information and the information regarding dosage in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42237), the maximum new technology add-on payment for ELZONRIS™ for FY 2022 would be $144,116.04, as reflected in the table in this section.

Comment: We received a few comments on our request for comment regarding technologies sold on a subscription basis and whether the cost per case should be estimated based on subscriber hospital data, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment. Commenters agreed that in determining the cost per case for technologies seeking new technology add-on payment that utilize a subscription model, we should limit our analysis to subscriber hospitals and update the cost analysis on an annual basis. A commenter noted that alternative methodologies involving estimating the number of patients who would be eligible to receive treatment utilizing a technology sold on a subscription basis would be likely to result in a payment amount that does not adequately reflect the estimated average cost of such service or technology as required by the statute. The commenter believes that given the direct impact of utilization changes on cost per case when using a subscription model, it is reasonable for CMS to annually update the payment amount using the most recent subscriber utilization data.

Response: We thank commenters for their comments and will take the comments into consideration in future rulemaking where applicable. CMS will continue to consider the issues pertaining to technologies sold on a subscription basis relative to the calculation of the cost per unit of these technologies including the merits of calculating the cost per case across all IPPS hospitals versus limiting the cost per case analysis to current users and whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment, as we gain more experience in this area.

However, for FY 2022, we believe the cost per case from the ContaCT applicant's original cost analysis is still appropriate to be used. Specifically, updated data from FY 2020 may be affected by the COVID–19 PHE as noted in our discussion in section I.A. where we finalize our policy to use the FY 2019 MedPAR data instead of the FY 2020 data. The applicant estimated that the average cost of ContaCT to the hospital is $1,600 based on customer data (85 FR 58630). Based on this information, the maximum new technology add-on payment for a case involving the use of ContaCT continues to be $1,040 for FY 2022.

As previously noted, we are finalizing our proposal to use FY 2019 data instead of FY 2020 data to develop the FY 2022 relative weights, as discussed in section I.F of the preamble of this final rule. For the reasons discussed previously, in light of this final policy, and after consideration of the public comments received, we are finalizing our proposal to use our authority under section 1886(d)(5)(I) of the Act to allow for a 1-year extension of new technology add-on payments for FY 2022 for the technologies listed in the proposed rule (except for Azedra® which is discussed above) and in the following table in this section of this final rule for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022. As we discussed previously, because of the unique circumstances associated with ratesetting for FY 2022, we believe it is appropriate to make a one-time exception to our long-standing policy for all technologies approved for new technology add-on payments for FY 2021, but for which the add-on payments would otherwise be discontinued beginning in FY 2022 because the technologies would no longer be considered new.

The following table lists the technologies for which we are finalizing this 1-year extension of new technology add-on payments for FY 2022, including the newness start date, new technology add-on payment start date, relevant final rule citations from prior fiscal years, maximum add-on payment amount, and coding assignments. We refer readers to the cited final rules in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

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One Year Extension for Technologies for which New Technology Add-on Payment Would Otherwise Be Discontinued in FY 2022							
	Technology	**FDA/Newness Start Date**	**NTAP Start Date**	**NTAP Status for FY 2022**	**Previous Final Rule Citations**	**Maximum NTAP Amount for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
1	*Cablivi®*	*02/06/2019*	*10/01/2019*	*One year extension; 3-year anniversary date (2/6/2022) will occur prior to the second half of FY 2022*	(84 FR 42201 through 42208) and (85 FR 58615)	$33,215	XW013W5, XW033W5 and XW043W5
2	*Elzonris™*	*12/21/2018*	*10/01/2019*	*One year extension;3-year anniversary date (12/21/2021) will occur prior to the second half of FY 2022*	(84 FR 42231 through 42237) and (85 FR 58615 through 58616)	$144,116.04	XW033Q5 and XW043Q5
3	*AndexXa™*	*05/03/2018*	*10/01/2018*	*One year extension; 3-year anniversary date (5/3/2021) will occur prior to the second half of FY 2022*	(83 FR 41355 through 41362), (84 FR 42193 through 42194) and (85 FR 58614 through 58615)	$18,281.25	XW03372 or XW04372
4	*Spravato®*	*3/5/2019*	*10/01/2019*	*One year extension; 3-year anniversary date (3/5/2022) will occur prior to the second half of FY 2022*	(84 FR 42247 through 42256) and (85 FR 58616 through 58617)	$1,014.79	XW097M5
5	*Zemdri®*	*6/25/2018*	*10/01/2018*	*One year extension; 3-year anniversary date (6/25/2021) will occur prior to the second half of FY 2022*	(83 FR 41326 through 41334), (84 FR 42190 through 42191) and 85 FR 58613)	$4,083.75	XW033G4 and XW04G4
6	*T2 Bacteria® Panel*	*05/24/2018*	*10/01/2019*	*One year extension; 3-year anniversary date (5/24/2021) will occur prior to the second half of FY 2022*	(84 FR 42278 through 42288) and (85 FR 58618)	$97.50	XXE5XM5
7	*ContaCT*	*02/13/2018 (commercially available 10/01/2018)*	*10/01/2020*	*One year extension; 3-year anniversary date (10/1/2021) will occur prior to the second half of FY 2022*	(85 FR 58625 through 58636)	$1,040	4A03X5D
8	*Eluvia™ Drug-Eluting Vascular Stent System*	*09/18/2018 commercially available in US 10/04/2018*	*10/01/2020*	*One-year extension; 3-year anniversary date (10/04/2021) will occur prior to the second half of FY 2022*	(85 FR 58645 through 58636)	$3,646.50	X27H385, X27H395, X27H3B5, X27H3C5, X27J385, X27J395, X27J3B5, X27J3C5, X27K385, X27K395, X27K3B5, X27K3C5, X27L385, X27L395, X27L3B5, X27L3C5
9	*Hemospray®*	*05/07/2018 (commercially available 07/01/2018)*	*10/01/2020*	*One-year extension; 3-year anniversary date (07/01/2021) will occur prior to the second half of FY 2022*	(85 FR 58665 through 58672)	$1,625	XW0G886 and XW0H886

One Year Extension for Technologies for which New Technology Add-on Payment Would Otherwise Be Discontinued in FY 2022							
	Technology	FDA/Newness Start Date	NTAP Start Date	NTAP Status for FY 2022	Previous Final Rule Citations	Maximum NTAP Amount for FY 2022	Coding Used to Identify Cases Eligible for NTAP
10	*IMFINZI®/ TECENTRIQ®*	*Imfinzi: 03/27/2020; Tecentriq: 03/18/2019 Newness date is 3/18/2019 for both*	*10/01/2020*	*One-year extension; 3-year anniversary date (03/18/2022) will occur prior to the second half of FY 2022*	(85 FR 58672 through 58684)	$6,875.90	Imfinzi XW03336 or XW04336 Tecentriq XW033D6 or XW043D6
11	*NUZYRA®*	*10/02/2018 (commercially available 02/01/2019)*	*10/01/2020*	*One-year extension; 3-year anniversary date (0(2/01/2022) will occur prior to the second half of FY 2022*	(85 FR 58725 through 58727)	$1,552.50	XW033B6 or XW043B6
12	*SpineJack® System*	*08/30/2018 (commercially available 10/11/2018)*	*10/01/2020*	*One-year extension; 3-year anniversary date (10/11/2021) will occur prior to the second half of FY 2022*	(85 FR 58689 through 58701)	$3,654.72	XNU0356 and XNU4356
13	*Xospata®*	*11/28/2018*	*10/01/2019*	*One-year extension; 3-year anniversary date (11/28/2021) will occur prior to the second half of FY 2022*	(84 FR 42256 through 42260) and (85 FR 58617)	$7,312.50	XW0DXV5

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5. FY 2022 Applications for New Technology Add-On Payments (Traditional Pathway)

We received 26 applications for new technology add-on payments for FY 2022. Four applicants withdrew their applications prior to the issuance of the FY 2022 IPPS/LTCH PPS proposed rule. Five applicants, Iovance Biotherapeutics, Omeros Corporation, Mallinckrodt Pharmaceuticals, Janssen Biotech, Inc., and Vericel withdrew their applications for lifileucel, narsoplimab, TERLIVAZ (terlipressin), ciltacabtagene autoleucel, and Nexobrid respectively, prior to the issuance of this FY 2022 IPPS/LTCH PPS final rule. In addition, in accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval or clearance by July 1 of each year prior to the beginning of the fiscal year for which the application is being considered. One applicant, Ischemia Care, LLC for ISC–REST, did not receive FDA approval for its technology by July 1, 2021. Therefore, ISC–REST is not eligible for consideration for new technology add-on payments for FY 2022. We are not including in this final rule the description and discussion of this application which was included in the FY 2022 IPPS/LTCH PPS proposed rule.

We note that we received public comments on the applications for technologies that were withdrawn. However, because these technologies are ineligible for new technology add-on payments for FY 2022 because their applications were withdrawn, we are not summarizing nor responding to public comments regarding the new technology criteria for these technologies in this final rule. A discussion of the 16 remaining applications is presented below.

a. Aidoc Briefcase for PE

Aidoc Medical Ltd. (Aidoc) applied for new technology add-on payments for Aidoc Briefcase for PE (''Briefcase for PE'') for FY 2022. According to the applicant, Briefcase for PE is an FDA cleared, artificial intelligence (AI)-based solution for triage and notification of suspected pulmonary embolism (PE) cases.

The applicant stated that the device assists hospitals and radiologists by flagging and communicating suspected positive findings of PE in computed tomography (CT) pulmonary angiography (CTPA) examinations, which prompts the radiologist to assess relevant Digital Imaging and Communications in Medicine (DICOM) imaging files, allowing suspect cases to receive attention sooner than otherwise would have occurred, which in turn improves clinical outcomes. According to the applicant, patients with PE or suspected PE typically present at hospital emergency departments (EDs). The applicant stated that for these patients, ED physicians complete a brief evaluation and order imaging, which typically includes CTPA. With Briefcase for PE, CTPA images are automatically forwarded to the applicant's cloud-based engine where they are analyzed by an AI algorithm. The applicant claims that when Briefcase for PE detects a suspected PE, the radiologist is alerted via the user interface of the Aidoc Worklist Application that is installed on the radiologist's desktop. The applicant asserted that the notification prompts the radiologist to review the CTPA images and communicate with the emergency room team currently caring for the patient so that the appropriate clinical action may be taken sooner than it would otherwise have occurred in the absence of the tool.

The applicant stated that acute PE is a severe manifestation of venous thromboembolism (VTE) and occurs when a blood clot (thrombus) forms in a vein and then dislodges and travels to the pulmonary arteries in the lungs. The applicant stated acute symptomatic PE can cause death within 1 hour of onset in up to 10 percent of cases[9] and it is

[9] Naess IA, Christiansen SC, Romundstad P, Cannegieter SC, Rosendaal FR, Hammerstrøm J.

Continued

estimated to be the third largest cause of cardiovascular death after coronary artery disease and stroke.[10, 11, 12, 13] The applicant further noted that acute PE is a life-threatening medical emergency that demands urgent intervention and clinical studies have demonstrated a strong correlation between time to communication of PE findings, treatment, and clinical outcomes.[14,15,16] According to the applicant, in a typical workflow, a patient presenting to a hospital with signs or symptoms of PE would move through the system as follows: (1) Patient presents with suspected PE to the ED; (2) Patient receives contrast-enhanced CTPA imaging; (3) Technologist processes and reconstructs the CT images and manually routes them to the hospital picture archiving and communication system (PACS); (4) The exam enters a first-in-first-out (FIFO) reading queue, where it awaits radiological interpretation; (5) Radiologist reads the CT images and makes the diagnosis of PE; (6) The radiologist informs the referring physician of positive PE either verbally or through the radiologist report; (7) ED physician and/or on-call pulmonologist decide on the management strategy; (8) If appropriate, the patient proceeds to treatment.

The applicant asserted that the FIFO workflow is the standard of care. The applicant stated that Briefcase for PE allows facilities to substantially shorten the period of time between when the patient receives CTPA imaging (Step 2) and when the radiologist informs the referring physician of positive PE (Step 5). The applicant stated that Briefcase for PE streamlines this workflow using AI to analyze CTPA images of the chest automatically and notifies the radiologist that a suspected PE has been identified, enabling the radiologist to review imaging and make diagnostic decisions faster by prioritizing these images for review in the queue.

With respect to the newness criterion, Briefcase for PE received FDA 510(k) clearance on April 15, 2019 to market the device under FDA 510(k) number K190072. The FDA clearance for Briefcase for PE was based on substantial equivalence to the legally marketed predicate device, Briefcase for Intracranial Hemorrhage (ICH) (FDA 510(k) number K180647), as both of these devices use AI algorithms to analyze images and highlight cases for further action based on CT images. Briefcase for ICH received FDA 510(k) clearance on August 1, 2018. The predicate device for Briefcase for ICH is Viz.AI's ContaCT, which received De Novo premarket approval in February of 2018. The applicant asserted Briefcase for ICH is indicated for use in the analysis of non-enhanced head CT images, whereas Briefcase for PE is indicated for use in the analysis of non-enhanced CTPA images. The applicant submitted a request for approval of a unique ICD–10–PCS procedure code to identify use of the technology and was granted approval for the following procedure code effective October 1, 2021: XXE3X27 (Measurement of pulmonary artery flow, computer-aided triage and notification, new technology group 7).

Under the newness criterion, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, Briefcase for PE is the only FDA-cleared technology that uses computer-aided triage and notification to rapidly detect PE and shorten time to notification of the radiologist. The applicant claimed that no other FDA approved or cleared technology uses the same mechanism of action for computer-aided triage and prioritization of PE.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated it expects that patients evaluated for PE or suspected PE using Briefcase for PE will be assigned to the same DRGs as patients evaluated for PE or suspected PE under the current workflow or standard of care. The applicant estimates that under the MS–DRG grouper for FY 2021, Briefcase for PE could map to 279 different MS–DRGs, with MS–DRGs 175 (Pulmonary embolism with major complication or comorbidity (MCC) or acute cor pulmonale) and 176 (Pulmonary embolism without MCC) accounting for approximately 45 percent of the estimated cases.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant did not directly respond to the criterion but reiterated that no other existing technology is comparable to Briefcase for PE and that Briefcase for PE is the only FDA-cleared technology that uses computer aided triage and notification to rapidly detect PE and shorten time to notification of the radiologist.

We noted the following concerns in the proposed rule (86 FR 25218) regarding whether the technology meets the substantial similarity criteria and whether it should be considered new. We noted that the applicant asserted that Briefcase for ICH, the predicate device for Briefcase for PE, is identical in all aspects and differs only with respect to the training of the algorithm on PE (that is, non-enhanced head CT) and ICH (that is, non-enhanced CTPA) images. We noted that we were unclear whether the training of the algorithim on PE and ICH images would distinguish the mechanism of action for Briefcase for PE from Briefcase for ICH, or its predicate device, ContaCT, and we invited comment on whether Briefcase for PE represents a new mechanism of action. We noted that although the applicant did not directly state whether Briefcase for PE involves the treatment of the same or similar type of disease and the same or similar patient population, we believe that Briefcase for PE would be used for a different disease and patient population than Briefcase for ICH and ContaCT.

We noted our interest in public comments regarding issues related to

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Incidence and mortality of venous thrombosis: a population-based study. *J Thromb Haemost.* 2007 Apr;5(4):692–9. doi: 10.1111/j.1538–7836.2007.02450.x. PMID: 17367492.

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[11] Becattini C, Agnelli G. Risk factors for adverse short-term outcome in patients with pulmonary embolism. *Thromb Res.* 2001 Sep 15;103(6):V239–44. doi: 10.1016/s0049–3848(01)00291–2. PMID: 11567661.

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[13] Klok FA, Mos IC, Huisman MV. Brain-type natriuretic peptide levels in the prediction of adverse outcome in patients with pulmonary embolism: A systematic review and meta-analysis. *Am J Respir Crit Care Med.* 2008 Aug 15;178(4):425–30. doi: 10.1164/rccm.200803–459OC. Epub 2008 Jun 12. PMID: 18556626.

[14] Smith SB, Geske JB, Maguire JM, Zane NA, Carter RE, Morgenthaler TI. Early anticoagulation is associated with reduced mortality for acute pulmonary embolism. *Chest.* 2010 Jun;137(6):1382–90. doi: 10.1378/chest.09–0959. Epub 2010 Jan 15. PMID: 20081101; PMCID: PMC3021363.

[15] Soh S, Kim JM, Park JH, Koh SO, Na S. Delayed anticoagulation is associated with poor outcomes in high-risk acute pulmonary embolism. J Crit Care. 2016 Apr; 32:21–5. doi: 10.1016/j.jcrc.2015.11.024. Epub 2015 Dec 8. PMID: 26764578.

[16] Wood KE. Major pulmonary embolism: review of a pathophysiologic approach to the golden hour of hemodynamically significant pulmonary embolism. *Chest.* 2002 Mar; 121(3):877–905. PMID: 11888976.

determining newness for technologies that use AI, an algorithm, or software, as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58628). Specifically, we stated that we are interested in public comment on how these technologies, including devices classified as radiological computer aided triage and notification software and radiological computer-assisted diagnostic software, may be considered for the purpose of identifying a unique mechanism of action; how updates to AI, an algorithm or software would affect an already approved technology or a competing technology; whether software changes for an already approved technology could be considered a new mechanism of action, and whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome is the same as an already approved AI new technology.

We invited public comments on whether Briefcase for PE is substantially similar to other technologies and whether Briefcase for PE meets the newness criterion.

Comment: The applicant submitted a letter maintaining that Briefcase for PE meets the newness criterion. With regard to commercial availability, the applicant commented that Briefcase for PE was commercially available on a very limited basis for less than six months during the FY 2019 time period of the data CMS is proposing to use to recalibrate MS–DRG weights and, therefore, that the claims from that time period do not reflect the cost of Briefcase for PE.

With respect to whether Briefcase for PE uses the same or a similar mechanism of action when compared to an existing technology, the applicant commented that the concern that Briefcase for PE is identical in all aspects to its predicate device, Briefcase for ICH, overlooks key components of the technology and the anatomy on which it focuses. The applicant cited the FDA definition of mechanism of action, which is ''the means by which a product achieves its intended therapeutic effect or action,'' in its assertion that the analysis of CTPA images for suspected findings of PE and subsequent computer-assisted triage and notification is the new mechanism of action. The applicant also noted that the images analyzed by the algorithm are of the pulmonary arteries, not of vessels in the brain as with Briefcase for ICH or ContaCT. The applicant stated that while AI is a necessary component of Briefcase for PE, it is not the mechanism of action per se, and is not sufficient to achieve the therapeutic effect alone.

With regard to the second and third newness criteria, the applicant commented that while Briefcase for PE and its predicate technologies are all AI-based triage and notification systems, these technologies are distinctly different in that the technologies focus on different patient populations and would be assigned to different MS–DRGs.

The applicant also responded to our question as to how AI, an algorithm, or software may be viewed as identifying a unique mechanism of action. The applicant concurred with other commenters in stating that such technologies should be evaluated for newness in the same way as CMS evaluates any other medical device applying for new technology add-on payment. That is, the commenters stated that human intelligence and human processes are not FDA approved or cleared technologies and should not be used as a comparator to evaluate whether Briefcase for PE, or any technology, meets the definition of newness. A commenter also noted that each of the AI technologies that applied for new technology add-on payments for FY 2022 are distinctly different in that the technologies focus on different patient populations and/or would be assigned to different MS–DRGs. This commenter stated, along with the applicant, that because there are no other technologies that have been approved or cleared by the FDA for the identification, triage and notification of suspected findings of PE that have been on the market for more than 2 to 3 years, Briefcase for PE meets the newness criterion.

A commenter noted how updates to an AI, an algorithm or software would affect an already approved technology or a competing technology. This commenter noted a phenomenon known as ''model drift,'' which can occur over time due to changes in healthcare workflows, practices, populations, and data. The commenter explained that when this occurs, the underlying algorithm does not automatically change and adapt to the new inputs, but its output predictions can become less accurate over time. The commenter further noted that model drift can be detected using the same statistical analyses that rigorously tested the algorithm's initial training data inputs and output predictions to ensure that they are free of statistically significant variances or biases. The commenter stated that if the AI/Machine Learning model or the algorithms that comprise the model change over time, they ideally should be subjected to this extensive statistical testing regimen that occurred before its original deployment, and developers should gauge the nature and extent of any model drift that occurs and make slight modifications if possible that would allow for its continued use in clinical care.

Response: We appreciate the clarification from the applicant with respect to whether the product meets the newness criterion. After consideration of the comments received and information submitted by the applicant as part of its FY 2022 new technology add-on payment application, at this time and given our ongoing consideration of assessing newness for technology that use AI, an algorithm or software, we believe that Briefcase for PE uses a new mechanism of action to achieve a therapeutic outcome when compared to existing treatments because there are currently no FDA approved or cleared technologies that analyze CTPA images for suspected findings of PE and subsequent computer-assisted triage and notification. Therefore, we believe that Briefcase for PE is not substantially similar to an existing technology and meets the newness criterion.

We also thank the commenters for their input on determining newness for technologies that use AI, an algorithm or software, as discussed in the proposed rule. We will continue consider how these technologies may be used to identify a unique mechanism of action; how updates to AI, an algorithm or software would affect an already approved technology or a competing technology; whether software changes for an already approved technology could be considered a new mechanism of action, and whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome is the same as an already approved AI new technology, as we gain more experience in this area.

With regard to the cost criterion, the applicant presented the following analysis. The applicant first identified the principal diagnoses associated with the PE-related MS–DRGs 175 (''Pulmonary embolism with MCC or acute cor pulmonale'') and 176 (''Pulmonary embolism without MCC''). The applicant then searched the FY 2019 proposed rule MedPAR Limited Data Set (LDS) for claims where the principal diagnoses were listed in any position on an inpatient claim. The applicant mapped the 2,517 identified claims to the list of unique MS–DRGs corresponding to these claims and aggregated the claims by MS–DRG. Per the applicant, under the MS–DRG grouper for FY 2021, potential cases representing patients who may be eligible for treatment using Briefcase for

PE map to 279 MS–DRGs, with MS–DRGs 175 and 176 accounting for approximately 45 percent of estimated cases. The applicant also provided a table of the top 10 MS–DRGs, which represent approximately 69 percent of estimated cases.

MS-DRG	MS-DRG Title
175	PULMONARY EMBOLISM WITH MCC OR ACUTE COR PULMONALE
176	PULMONARY EMBOLISM WITHOUT MCC
871	SEPTICEMIA OR SEVERE SEPSIS WITHOUT MV >96 HOURS WITH MCC
299	PERIPHERAL VASCULAR DISORDERS WITH MCC
208	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT <=96 HOURS
291	HEART FAILURE AND SHOCK WITH MCC
280	ACUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE WITH MCC
163	MAJOR CHEST PROCEDURES WITH MCC
270	OTHER MAJOR CARDIOVASCULAR PROCEDURES WITH MCC
853	INFECTIOUS AND PARASITIC DISEASES WITH O.R. PROCEDURES WITH MCC

The applicant standardized the charges and applied the 2-year charge inflation factor used to adjust the outlier threshold determination, which the applicant stated was 10.22 percent. We note that the actual 2-year inflation factor in the FY 2021 IPPS/LTCH PPS final rule was 13.2 percent (85 FR 59039), which would have increased the inflated charges figure. The applicant did not remove charges for prior technology as the applicant maintained that no existing technology is comparable to Briefcase for PE. However, the applicant removed 31.9 percent of total accommodation charges, which the applicant maintained is consistent with their internal study which indicated that Briefcase for PE reduced the length of stay for PE-diagnosed patients.[17] Per the applicant, the study demonstrated a mean length of stay of 8.77 and 5.97 days for pre-AI and post-AI time periods, respectively.[18]

Next, the applicant added charges for the new technology. To calculate the charges for the new technology, the applicant multiplied the cases involving Briefcase for PE from each of its subscribing providers by a Medicare share of 52 percent to obtain the total estimated Medicare and non-Medicare cases. The applicant obtained the 52 percent Medicare share figure from a nationwide sample of inpatient claims provided by the Agency for Healthcare Research and Quality (AHRQ). Specifically, the applicant searched data from the Healthcare Cost and Utilization Project for discharges with the following codes: I2699, I2609, I2692, I2602, I2782, T790XXA, T800XXA, T791XXA, I2693, I2694, and I2601.[19] The applicant found 189,575 discharges, of which 52 percent identified Medicare as the payer. The applicant divided the total cost of the technology by the estimated total number of cases for each customer to obtain a provider-specific cost per case, which it then averaged across all customers to obtain an overall average cost per case. Finally, the applicant divided the average cost per case by the national average CCR for the CT cost center of 0.034 from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601).

The applicant calculated a final inflated average case-weighted standardized charge per case of $87,483, which exceeded the average case-weighted threshold amount of $71,312. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that Briefcase for PE meets the cost criterion.

We stated in the proposed rule (86 FR 25219) that we would like more information regarding the methodology by which the applicant selected the diagnosis codes associated with MS–DRGs 175 and 176, as well as subanalyses that limit the cases to MS–DRGs 175 and 176 and the top 10 MS–DRGs, which per the applicant represent 45 percent of estimated cases and 69 percent of estimated cases, respectively. Additionally, we noted that the applicant appeared to have used a single list price of Briefcase for PE per hospital with a cost per patient that can vary based on the volume of cases. We questioned whether the cost per patient varied based on the utilization of the technology by the hospitals. We stated that we were interested in more information about the applicant's cost per case calculation, including how the applicant selected the codes it used to search for discharges from the Healthcare Cost and Utilization Project, as well as the per unit cost of Briefcase for PE and how the total cost of the technology was calculated for each subscribing provider.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58630), we stated our

[17] Maya M. et al. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduced Length of Stay. Abstract draft of an internal study performed by the applicant (unpublished).

[18] Ibid.

[19] Healthcare Cost and Utilization Project. Free Health Care Statistics. *https://hcupnet.ahrq.gov/#setup*.

understanding that there are unique circumstances to determining a cost per case for a technology that utilizes a subscription for its cost. We stated our intent to continue to consider the issues relating to the calculation of the cost per unit of technologies sold on a subscription basis as we gain more experience in this area. In the FY 2022 IPPS/LTCH PPS proposed rule, we continued to welcome comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment. We also invited public comment on whether Briefcase for PE meets the cost criterion, particularly in light of the subscription model, for which the number of subscribers and the estimated cost per case based on that subscriber data may change over time.

Comment: The applicant submitted a comment in response to our concerns in the proposed rule regarding the methodology for conducting the cost analysis for Briefcase for PE. With respect to our inquiry regarding the specific MS–DRGs selected for the analysis and the reasoning for selecting the identified ICD–10–CM diagnosis codes, the applicant explained that because Briefcase for PE is a new technology, there is no current utilization available for analysis and that, additionally, CT pulmonary angiogram, the imaging procedure that is specific to Briefcase for PE, is not reliably reported in the inpatient setting using ICD–10–PCS procedure codes. Therefore, to estimate the potential utilization of Briefcase for PE among Medicare beneficiaries, the applicant stated that it used a multi-step approach that involved identifying MS–DRGs specific to pulmonary embolism and determining the principal diagnoses associated with those MS–DRGs. The applicant determined the principal diagnoses associated with MS–DRG 175 (''Pulmonary embolism with MCC or acute cor pulmonale'') and MS–DRG 176 (''Pulmonary embolism without MCC'') and re-examined those diagnosis codes used in the initial calculation. The applicant decided to eliminate claims with the ICD–10–CM diagnosis of I27.82 (chronic pulmonary embolism) as it does not reflect incidental pulmonary embolism, the type of suspected positive cases that Briefcase for PE is intended to flag. The applicant then searched for all claims where the remaining principal diagnoses were listed as a diagnosis in any position on the claim, including the admitting diagnosis. Based on this methodology, the applicant aggregated the claims by MS–DRG and compiled a list of unique MS–DRGs corresponding to these claims. Per the applicant, the total claims for those providers who currently use Briefcase for PE were then aggregated by these MS–DRGs.

With respect to our inquiry regarding the applicant's cost per case methodology, the applicant clarified that the cost per case for each provider was not based on a single list price per hospital, as CMS described in the proposed rule, but rather the individual customer's specific list price based on the applicant's actual pricing. The applicant explained that it calculated the cost per case for each provider using the individual list price and total Medicare and non-Medicare cases, before taking an average of these unique costs per case to derive an average cost per case across all users, which the applicant then converted to charges.

In response to concerns CMS previously raised and continues to raise concerning variation in the cost per patient for a technology with subscription-based pricing, the applicant acknowledged that the cost per patient may change as the applicant adds more customers. The applicant conducted additional analyses beyond the one submitted in its new technology add-on payment application to examine how the cost per patient varied when data from all IPPS hospitals are included, versus the sample of subscriber hospitals used in its original analysis. According to the applicant, these analyses were performed using the methodology described in detail in the proposed rule with two additional changes: The elimination of ICD–10–CM code I27.82 as noted previously and an inflation factor of 13.2 percent instead of 10.22 percent. The applicant stated that it calculated the cost per patient by dividing the total cost of Briefcase for PE per year per hospital by the number of total estimated cases for which Briefcase for PE would be used at each hospital, and then averaging across all such hospitals. The applicant noted that it took a conservative approach and used the lowest pricing tier for hospitals that are not current users of the technology. After excluding hospitals with fewer than 11 cases, the applicant calculated a cost per case across 2,187 general acute care hospitals that was higher than the cost per case across subscriber hospitals. In updating its analysis, the applicant noted that the final inflated average case-weighted standardized charge per case is $104,688 which exceeded the case-weighted threshold amount of $71,507.

The applicant conducted two additional analyses for all current hospital clients and for all IPPS hospitals. For these analyses, the applicant calculated an average cost per case using the methodology described previously as well as a case-weighted average cost per case where the average was determined by assigning weight to each institution in relation to their relative importance and/or significance. Per the applicant, the additional analyses use the same methodology described previously but limit the cases included. Under the first alternative analysis, the applicant limited cases to only those in the top 10 MS–DRGs by volume. Under the second alternative analysis, the applicant limited cases to only those in the two pulmonary embolism MS–DRGs (MS–DRG 175 and 176). Under each scenario, the applicant determined that the final inflated case-weighted standardized charge per case exceeded the case-weighted threshold.

Category	Cost Analysis: Average Cost per Case		Cost Analysis: Case-Weighted Average Cost per Case	
	Case Weighted Threshold	Final Inflated Case Weighted Standardized Charge Per Case*	Case Weighted Threshold	Final Inflated Case Weighted Standardized Charge Per Case*
Current hospital users				
All MS-DRGs	$ 71,507	$ 90,513	$ 71,507	$ 90,221
Top 10 MS-DRGS	$ 57,251	$ 72,534	$ 57,251	$ 71,602
MS DRGs 175 and 176	$ 49,378	$ 63,803	$ 49,378	$ 61,338
All IPPS hospitals				
All MS-DRGs	$ 71,507	$ 167,942	$ 71,507	$ 98,140
Top 10 MS-DRGS	$ 57,251	$ 161,651	$ 57,251	$ 81,344
MS DRGs 175 and 176	$ 49,378	$ 169,173	$ 49,378	$ 73,071

* Calculated using cost per case before suppression of small cell sizes

Response: We thank the applicant for its input. We note that the applicant did not specify how it determined the relative weight and importance of institutions when calculating the case-weighted cost per case in its supplemental analyses; although it appears to have been determined based on each institution's case volume relative to others in the sample, we would appreciate a clarification in the future. However, we agree with the applicant that the final inflated case-weighted standardized charge per case exceeded the case-weighted threshold under the twelve scenarios presented in its original application and in response to our concerns stated in the FY 2022 IPPS/LTCH PPS proposed rule. Therefore, we agree with the applicant that Briefcase for PE meets the cost criterion.

Comment: The applicant also responded to CMS' request for public comment as to the appropriate method to determine a cost per case for technologies sold on a subscription basis, including whether the cost per case should be estimated based on subscriber hospital data and, if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment. The applicant concurred with other commenters that, in determining the cost per case for technologies seeking new technology add-on payment that utilize a subscription model, we should limit our analysis to subscriber hospitals and update the cost analysis on an annual basis. The applicant also concurred that alternative methodologies involving estimating the number of patients who would be eligible to receive treatment utilizing a technology sold on a subscription basis would be likely to result in a payment amount that does not adequately reflect the estimated average cost of such service or technology as required by Section 1886(d)(5)(K)(ii)(III) of the Act.

According to the applicant, technologies sold on a subscription basis are provided to the customer at a fixed price per period of time, resulting in a cost per unit that is directly impacted by the frequency that the customer utilizes the technology. The applicant explained that customers with low utilization of a subscription-based technology have a higher cost per unit than customers with high utilization. The applicant also stated that because the overall cost per unit of subscription technologies is determined by each customer's ratio of price to utilization, an analysis that requires an estimate of cost per unit should be limited to subscribers only, as including estimates of cost per unit for potential customers that do not currently subscribe to the technology may result in a cost-per-case that does not reflect the actual costs of current users. The applicant recommends that the cost per unit of technologies sold on a subscription basis should be based on data from

current subscribers only and that yearly updates to the cost per unit analysis are reasonable to reflect changes in subscribers and thus the overall cost per unit.

The applicant stated that this recommendation is consistent with how CMS calculates costs across a variety of payment systems and programs, including MS–DRG relative weights and APC relative weights where CMS only considers costs from hospitals for cases billed to Medicare and does not attempt to estimate what the cost an MS–DRG or APC relative weight might be if a broader range of hospitals delivered the type of care described by a specific MS–DRG or APC. Similarly, the applicant stated that the average sales price methodology used by CMS to determine payment for certain separately payable products includes only data from actual customer sales. The applicant noted that, although the unit price for these separately payable products often varies based on utilization, with customers with low utilization paying more per unit than customers with higher utilization, CMS does not attempt to calculate average sales price by forecasting how future customers may alter the current average sales price.

Response: We appreciate the applicant's comments relating to calculation of the cost per unit of technologies sold on a subscription basis and will take the comments into consideration in future rulemaking where applicable. CMS will continue to consider the issues pertaining to technologies sold on a subscription basis relative to the calculation of the cost per unit of these technologies including the merits of calculating the cost per case across all IPPS hospitals versus limiting the cost per case analysis to current users and whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment, as we gain more experience in this area.

With regard to the substantial clinical improvement criterion, the applicant claimed that Briefcase for PE represents an advance that substantially improves the ability to diagnose pulmonary embolism by pre-reading images of CTPAs, automatically identifying suspected PE in CTPA images, and notifying the radiologist before the radiologist would have opened the study in the standard of care, which the applicant claims is the FIFO workflow. The applicant also asserted that because of a reduction in time-to-exam-open, where Briefcase for PE notifies the radiologist to open and read CTPA studies that have a high probability of being positive for PE sooner than the radiologist would have under the FIFO workflow, the treating physician can initiate treatment sooner, which can reduce mortality and reduce length of stay related to PE.

The applicant provided data from an FDA pivotal study in support of its assertion that Briefcase for PE reduces time-to-exam-open compared to the standard of care and helps in prioritization of diagnosis.[20] For the FDA pivotal study, the applicant conducted a retrospective, blinded, multicenter, multinational study of the assessment of 184 CTPAs from 3 clinical sites (2 U.S. and 1 outside U.S.) using Briefcase for PE. The primary endpoint was to evaluate the software's performance in identifying pulmonary embolism on an approximately equal number of positive and negative cases (images with PE versus without PE), with a performance goal of at least 80 percent sensitivity (true positive rate) and specificity (true negative rate). Per the applicant, both measures exceeded the performance goal, with 90.6 percent sensitivity (95 percent CI: 82.2 percent–95.9 percent) and 89.9 percent specificity (95 percent CI: 82.2 percent–95.1 percent).

According to the applicant, the secondary endpoint of the FDA pivotal study was to evaluate time-to-notification for true positive PE cases compared to the FIFO workflow. The study showed that time-to-notification with Briefcase for PE is 3.9 minutes (95 percent CI: 3.7–4.1). The applicant noted that, in contrast, the time-to-exam-open in the FIFO workflow was significantly longer at 64.1 minutes (95 percent CI 36.6–91.5). The applicant stated the mean difference of 60.2 minutes (95 percent CI 32.7–87.6) for these two metrics is statistically significant, and assuming the radiologist receives a notification on a true positive PE case and acts on it immediately, it can save an average of 60.2 minutes (95 percent CI 32.7–87.6) compared to the time-to exam-open in a FIFO reading queue. Based on this data, the applicant concluded Briefcase for PE substantially shortened the time to diagnosis for PE cases as compared with the FIFO workflow.

The applicant further claimed that clinical studies and other real-world data have demonstrated comparable performance characteristics and shown that the integration of the Briefcase for PE software into the radiology workflow markedly improves time to notification for PE patients across a variety of clinical settings, geographies, and facilities. The applicant submitted a retrospective, single-site study by Weikert T., et al., which evaluated Briefcase for PE performance on 1,465 retrospective CTPA examinations from 2017 in an academic center outside the US.[21] The sensitivity and specificity were measured to be 92.7 percent (95 percent CI: 88.3–95.5 percent) and 95.5 percent (95 percent CI:94.2– 96.6 percent), respectively. The researchers concluded that the system has high diagnostic performance for the automatic detection of PE on CTPA exams and as such, speeds up the diagnostic workup of critical cases.

The applicant stated that unpublished data maintained by Aidoc suggest that real-world performance of Briefcase for PE is consistent with what was found in the FDA pivotal study.[22] [23] The applicant stated that across 26 sites encompassing a variety of geographic locations across the United States, a total of 36,084 CTPA examinations were analyzed over a 90-day period (July 13, 2020–October 11, 2020). Time-to-notification metrics were calculated for all 4,748 CTPAs analyzed by the software and identified as positive for PE. Time-to-notification was calculated as the time to get the DICOM exam, de-identify it, upload it to the cloud, analyze and send a notification back to the worklist application. The applicant claimed that the mean time-to-notification for PE was 7.0 minutes (median: 6.1/IQR: 4.8). According to the applicant, over 85 percent of CTPA examinations identified as positive for PE were notified in under 10 minutes. The applicant concluded that the study demonstrates the ability of Briefcase for PE to provide fast time-to-notification on positive PE cases and its generalizability across different centers and patient populations.

The applicant submitted additional unpublished data from the 26 sites spread across a variety of geographic locations of the United States aggregated over a different 90-day period (September 17, 2020 to December 17,

[20] Aidoc Briefcase for PE—Pivotal Study 1—FDA 510(k)—K190072. *http://www.accessdata.fda.gov/cdrh_docs/pdf19/K190072.pdf.*

[21] Weikert T, Winkel DJ, Bremerich J, Stieltjes B, Parmar V, Sauter AW, Sommer G. Automated detection of pulmonary embolism in CT pulmonary angiograms using an AI-powered algorithm. *Eur Radiol.* 2020 Jul 3. doi: 10.1007/s00330–020–06998–0. Epub ahead of print. PMID: 32621243

[22] Avondo, J. Yalon R., Ashkenasi C. Time-to-notification Analysis Across US Facilities with Aidoc Briefcase for PE. Internal study performed by the applicant (unpublished).

[23] Ibid.

2020).[24] Seven sites were excluded from the analysis due to having third-party integrations that prevented the ability to capture engagement metrics. Two engagement metrics were calculated: The open percentage and the time-to-open. The open percentage metric was calculated as the percentage of notifications that were presented to the radiologist and opened by at least one radiologist. The time-to-open metric was measured by calculating the time between the arrival of the Briefcase for PE notification and the time first opened by a radiologist. A total of 2,138 notifications for CTPA examinations found to be positive for PE by Briefcase for PE were analyzed. The open percentage was found to be 97 percent across all sites (min: 80 percent, max: 100 percent), and the mean time-to-open was found to be 2.13 minutes (median: 1.0/interquartile range: 2.0). The data provided by the applicant indicated over 90 percent of notifications were found to be opened in under 5 minutes. Based on this data, the study concluded that radiologists in the US readily engage with notifications for positive PE cases provided by Briefcase for PE and do so in a timely manner. The study asserted that engagement is an important metric to assess radiologist adoption of this technology, which is critical to its practical utility in shortening time to diagnosis and communication of PE to reduce the time to treatment and improve clinical outcomes.

The applicant also claimed that Briefcase for PE significantly improves clinical outcomes relative to the current standard of care using the FIFO workflow because the use of Briefcase for PE reduces time to diagnosis and treatment by notifying the radiologist to review the image for suspected PE faster in the workflow. The applicant claimed early diagnosis and treatment is important in acute PE where there exists a ''golden hour,'' during which a timely approach to diagnosis and therapy can affect outcomes by reducing mortality and reducing length of stay.[25]

The applicant provided two unpublished internal studies in support of the impact of Briefcase for PE on clinical outcomes. The applicant stated that in a single-site retrospective study, Maya M., et al. have shown a reduction in hospital length of stay for PE patients following the use of the Briefcase for PE system, compared to an equivalent time period prior to the use of the system.[26] The applicant stated that Maya M., et al. compared mean length of stay for 366 patients with a positive PE diagnosis during 10-month periods before and after Briefcase for PE was implemented at Cedars-Sinai Medical Center in December 2018 (206 patients before the use of Briefcase for PE and 160 patients after the AI intervention). 3,997 patient encounters that underwent CTPA imaging but that were not diagnosed with PE were split as 1,926 and 2,071 patient encounters for the pre/post-AI periods based on the admission dates. Hip fracture was chosen as a comparison group due to acuity, treatment-related factors, and similar length of stay to PE. 2,422 patient encounters for patients diagnosed with hip fractures, identified by ICD9 code 820 and 821, were split as 1,279 and 1,143 patient encounters for the pre/post-AI periods based on the admission dates. According to the applicant, the pre- and post-implementation had similar seasonality and numbers of ''hospital-wide patient encounters'' (103,626 vs 104,733 encounters). The applicant noted that for the PE diagnosed patients, a mean length of stay of 8.77 and 5.97 days was observed for the pre-AI and post-AI time periods, respectively. The applicant stated that the mean difference was 2.80 days (p-value <0.05). For the group that underwent related PE imaging but was not diagnosed with PE, a mean length of stay of 9.28 and 9.70 days was observed for the pre-AI and post-AI time periods, respectively (mean difference was -0.42 days (p-value <0.05)). For the hip fracture diagnosed patients, a mean length of stay of 6.90 and 6.69 days was observed for the pre-AI and post-AI time periods, respectively. The mean difference was 0.21 days (p-value > 0.05). Additionally, for the hospital wide patients, a mean length of stay of 5.78 and 5.96 days was observed for the pre-AI and post-AI time periods, respectively. The mean difference was -0.18 days (p-value <0.05). According to the applicant, Maya et al. concluded that implementation of Briefcase for PE for flagging and prioritization of patients with PE resulted in significant reduction of length of stay that was not observed in other control groups.

The applicant also submitted a study by Raskin D., et al. which completed an additional retrospective, single-armed, single-site, study that indicated improved outcomes in PE patients, compared to a time period prior to the use of Briefcase for PE.[27] In Raskin D., et al., data for all patients older than 18 years with a diagnosis of PE on CTPA and admitted to the institution's ED was collected for the period before the use of the AI software (January 1, 2016–January 1, 2018; pre-AI) and afterwards (January 1, 2019–December 6, 2019; post-AI). According to the applicant, study variables included demographics, clinical data, and imaging data. The applicant stated the primary variables for outcomes were 30- and 120-day all-cause mortality. 175 patients were eligible for the entire analyzed period (123 pre-AI, 52 Post-AI). The study found that 30- and 120-day all-cause mortality were significantly reduced post-AI (8.1 percent vs 7.7 percent, 15.5 percent vs 9.6 percent, respectively, p <0.05). According to the applicant, Raskin D., et al. concluded that implementation of Briefcase for PE for flagging patients with PE resulted in significant reduction of 30- and 120-day all-cause mortality.

The applicant submitted five additional clinical studies that do not directly involve the use of Briefcase for PE to demonstrate a strong correlation between time to communication of PE findings, initiation of treatment, and clinical outcomes. The applicants submitted a review by Kenneth E. Wood, further establishing a ''golden hour'' of PE during which a timely approach to diagnosis and therapy can potentially impact outcomes. According to the applicant, Wood states that major PE results whenever the combination of embolism size and underlying cardiopulmonary status interact to produce hemodynamic instability and that most deaths in patients occur within the first few hours after presentation, and rapid diagnosis and treatment is therefore essential to save patients' lives. One prospective, single-site study, Kumamaru K., et al. indicates the prevalence of a ''golden hour'' for PE diagnosis and treatment and concluded that delay (≤ 1.5 hours of CTPA acquisition) in direct communication of acute PE diagnosis from radiologists to referring physicians was significantly correlated with a higher risk of delayed treatment initiation and death within 30 days. Another prospective, single-site study, Kline J., et al., concluded that

[24] Avondo, J. Yalon R., Ashkenasi C. Radiologist Engagement Analysis Across US Facilities with Aidoc Briefcase for PE. Internal study performed by the applicant (unpublished).

[25] The term ''golden hour'' references a critical period of time which may be longer or shorter than a literal hour.

[26] Maya M. et al. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduced Length of Stay. Abstract draft of an internal study performed by the applicant (unpublished).

[27] Daniel Raskin D., MD, Chen Hoffmann C., MD, Gilad Twig G., MD Ph.D., Eli Konen E., MD, Gal Yaniv GMD Ph.D. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduction of Mortality. Abstract draft of an internal study performed by the applicant (unpublished).

patients with a delayed diagnosis had a higher rate of in-hospital adverse events (9 percent vs. 30 percent; p = 0.01). An additional retrospective, single-site study by Smith S., et al. observed an association between early administration of anticoagulation therapy and reduced mortality for patients with acute PE. Lastly, a retrospective, single-site study asserting a ''golden hour'' by Soh S., et al. was submitted by the applicant to demonstrate an association between early initiation of anticoagulation therapy and in-hospital mortality in high-risk PE patients who needed ICU care. According to the applicant, Soh S., et al. concluded that their analysis showed that the cutoff point of anticoagulation initiation to achieve improved survival rates was 5.2 hours (that is, golden hour). The applicant stated that the study observed an association between early anticoagulation and reduced mortality for patients with acute PE.

In reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for Briefcase for PE, we noted that the clinical literature provided by the applicant only compares the technology to unassisted FIFO workflows and not against existing electronic (for example, EHR ''stat'' orders) or manual (for example, verbal communication to radiologist) forms of prioritization, or other types of existing risk stratification tools or features currently available in EHRs. Additionally, we noted that some of the studies provided by the applicant that took place over many years may not have accounted for confounding variables (for example, improvements in care for patients with suspected PE) that may have occurred during the study period. Comparing to the FIFO workflow alone assumes that no other changes occurred before and after the adoption of the system and that the hospitals in question did not implement any other changes to their standard operating procedures to stratify suspected PE cases over the period of time many of the provided studies took place. We also noted that the applicant has not provided data on potential outcome concerns associated with this type of clinical decision support tool (for example, treatment delays due to false negatives, false positives, or multiple workflow prioritization alerts presented to the physician at the same time). We invited public comment on whether these issues may affect the tool's ability to help diagnose a medical condition earlier in a patient population.

Lastly, we noted that the applicant does not measure the effect of its technology on actual treatment outcomes, instead relying on the assumption that faster treatment results in better outcomes. Without measuring this impact on treatment outcomes, we noted that we were uncertain if the technology will lead to substantive clinical outcomes. Given that the applicant references a critical ''golden hour'' which may be as long as 5.2 hours, the potential time savings resulting from the use of Briefcase for PE may be insubstantial in relation to the time within which outcomes are affected in the setting of PE.

We invited public comments on whether Briefcase for PE meets the substantial clinical improvement criterion.

Comment: Several commenters indicated their support for Briefcase for PE. Some of these commenters offered their general positive clinical experiences as anecdotal support for the product. Other commenters offered opinions that the tool reduces bias, improves knowledge sharing, reduces treatment time, and improves outcomes with patients with pulmonary embolism but did not provide comparison to anything other than FIFO workflow. Further, commenters reflected on the accuracy of the tool due to its high sensitivity and specificity, and others noted that it can help to alleviate situations where radiology departments are overwhelmed with orders by helping staff to prioritize the workflow.

Response: We appreciate all of the comments received related to Briefcase for PE and have taken them into consideration in making our determination.

Comment: The applicant submitted comments in response to CMS' concerns in the FY 2022 IPPS/LTCH PPS proposed rule regarding whether Briefcase for PE meets the substantial clinical improvement criterion.

In response to questions raised at the Town Hall, as referenced in the proposed rule (86 FR 25221 through 25222) as to whether the shortening of time to notification by Briefcase for PE represents substantial clinical improvement, the applicant reiterated data shared previously from the FDA Pivotal Study for Aidoc Briefcase for PE.[28] The applicant conducted a blinded, multi-center, multi-national study with Briefcase for PE that used the software's performance in identifying CTPAs containing pulmonary embolism as the primary endpoint, and time to notification for true positive PE cases compared to the standard of care as the secondary endpoint. The applicant noted a statistically significant mean difference of 60.2 minutes in time-to-notification between Briefcase for PE and the standard of care. Per the applicant, these data indicate that implementation of Briefcase for PE saves 60.2 minutes relative to the standard of care clinical workflow. The applicant further noted that data collected by the applicant in an unpublished study demonstrate that the real-world performance of Briefcase for PE is consistent with the results achieved in the aforementioned FDA study. Specifically, the applicant noted that across 4,748 CTPA examinations analyzed by Briefcase over a 90-day period and positive for PE, that the mean time-to-notification was seven minutes. The applicant also examined how radiologists engage with Briefcase for PE, noting that across 2,795 CTPA examinations analyzed by Briefcase over a 90-day period and positive for PE, the mean time-to-open as measured by calculating the time between when a notification first becomes available and the time of open, was 2.13 minutes. In this same data, the mean open rate across all customers were found to be 97 percent, and that over 90 percent of notifications were found to be opened in under 5 minutes. The applicant asserted in light of this data that by identifying cases of suspected PE and triaging and notifying radiologists of such cases, Briefcase for PE substantially shortens the time to diagnosis and therefore can impact the time to treat PE cases compared to the standard of care.

Further, the applicant submitted additional clinical evidence from Bader et al,[29] that demonstrates that implementation of Briefcase for PE resulted in significant reduction of time to anticoagulation and reduction in length of stay in patients diagnosed with PE who were administered anticoagulation (intravenous or subcutaneous). In Bader et al, the study evaluated patient records prior to and following installation of Briefcase for PE, analyzing time to anticoagulation and patient length of stay. A total of 118 patients diagnosed with PE–77 pre-installation and 41 post-installation– were identified. The study found a 23.8-minute reduction in mean time to

[28] Aidoc Briefcase for PE—Pivotal Study 1—FDA 510(k)—K190072

[29] Bader AS. ''Artificial Intelligence software for flagging Pulmonary Embolism on CTPA is associated with a reduced Time to Anticoagulation and reduced Hospital Length of Stay.'' Unpublished manuscript submitted for publication.

anticoagulation following the installation of Briefcase for PE from 61.74 minutes to 37.92 minutes. The study also found a 1.56 day reduction in mean length of stay following the installation of Briefcase for PE from 5.71 days to 4.15 days.

In response to our concerns about using FIFO workflow as the standard of care against which Briefcase for PE was evaluated, the applicant stated that other forms of prioritization such as verbal communication or STAT orders have limitations. The applicant stated that verbal communication is typically used only in severe cases, which are rare and represent less than 5 percent of positive PE cases. The applicant also stated that most patients diagnosed with PE have less severe clinical signs and symptoms at the time of presentation, making verbal communication impossible without the determination of the absence or presence of PE using CTPA.[30] The applicant asserted that STAT orders can be overused, citing one article published by Fairview Health Services that up 70% of all portable chest x-rays are ordered STAT,[31] and another article citing data from Emory University that up to 60% of all brain MRI studies are ordered as STAT and demonstrated that the STAT designation had a negative effect on read time.[32] The applicant stated that this overuse of STAT orders would reduce the benefit of the prioritization method. The applicant stated that many Briefcase for PE customers in fact rely on the product to re-prioritize the STAT cases using the additional insight from the AI image-based triage and prioritization.

In response to our concerns that the applicant had not discussed any potential outcome concerns associated with this type of clinical decision support tool, the applicant reasserted its position from the Town Hall that the device is not intended to diagnose PE, and as a triage and notification system, no patient harm results from suspected false positive or negative findings because the radiologist would review images to make final determinations per the standard of care. The applicant cited post-market surveillance data, which show that there have been zero reports of adverse effects since FDA clearance, to support the notion that Briefcase for PE has not led to significant changes in the volume of CTPAs ordered prior to and following installation.[33] [34]

In response to our concerns on the impact of the use of Briefcase for PE on treatment outcomes and whether a reduction in time of notification translates into a positive treatment outcome and thus a substantial clinical improvement, the applicant submitted data shared previously from Raskin et al,[35] Bader et al.,[36] Maya et al.,[37] that indicated a reduction on 120-day and 30-day mortality respectively; and reductions in length of stay after the introduction of Briefcase for PE into the clinical workflow. Specifically, in Raskin et al. the retrospective study examined the impact of the use of Briefcase for PE on outcomes in PE patients. This study involved a retrospective analysis of 1,258 patient medical records for cases performed over the two time periods and observed statistically significant reductions of 21.8% and 26.6% in 120-day and 30-day mortality respectively. Additionally, both Maya et al and Bader et al observed statistically significant reductions in length of stay when comparing pre and post-implementation of Briefcase for PE and found observed reductions of 26.3% and 27.3% in length of stay respectively.

Response: We appreciate the additional data shared by the applicant to address our concerns. However, after review of all the data received to date, we continue to have concerns regarding the substantial clinical improvement criterion as noted in the FY 2022 IPPS/LTCH PPS proposed rule. Specifically, it remains unclear if the data provides sufficient evidence that use of Briefcase for PE significantly improves clinical outcomes for PE patients as compared to currently available workflows. While the applicant provided evidence that implementation of Briefcase for PE resulted in significant reduction of time to anticoagulation and reduction in length of stay in patients diagnosed with PE who were administered anticoagulation, we note that the studies submitted by the applicant did not directly assess outcomes using the technology but rather relied on the assumption that faster treatment leads to better outcomes. We also note that studies submitted in support of the applicant's substantial clinical improvement claims compare the technology to unassisted (FIFO) workflows and do not account for existing electronic (for example EHR ''STAT orders'') or manual (for example verbal communication to radiologist) forms of prioritization. We note the applicant's statement that STAT orders may be overused but the evidence provided was from other imaging studies and not for CTPA. Additionally, some of the studies provided by the applicant took place over separate time periods and may not have accounted for improvements in care for patients with suspected PE that may have occurred during the study period.

Therefore, after consideration of the public comments we received and based on the information stated previously, we remain unable to determine that Briefcase for PE represents a substantial clinical improvement over existing therapies, and we are not approving new technology add-on payments for the Briefcase for PE for FY 2022.

b. RYBREVANT™ (amivantamab)

Johnson & Johnson Health Care Systems, Inc. applied for new technology add-on payments for RYBREVANT™ (amivantamab) for FY 2022. RYBREVANT™ is intended for the treatment of metastatic non-small cell lung cancer (NSCLC). The applicant stated RYBREVANT™ is a bispecific monoclonal antibody able to inhibit the epidermal growth factor receptor (EGFR) and c-MET tyrosine kinase signaling pathways known to be involved in the pathogenesis of NSCLC. Per the applicant, RYBREVANT™ works by binding EGFR and c-MET targets present on the outside of the cell. The applicant noted lung cancer is the second most common cancer in the U.S., and approximately 85 percent of all lung cancers are NSCLC. The applicant stated EGFR mutations are present in 10 to 15 percent of patients with NSCLC and are categorized as either common EGFR mutations or atypical EGFR mutations. Per the applicant, common EGFR mutations in patients with NSCLC can be treated with small molecule, oral tyrosine kinase inhibitors that work inside the cell while patients with atypical EGFR

[30] Kucher N, Rossi E, De Rosa M, and Goldhaber S. Massive Pulmonary Embolism. *Circ* J. 2006;113:577–582.

[31] Wesp W. Using STAT Properly. Radiology Management 2006;26–33. *https://www.ahra.org/AM/Downloads/OnlineEd/2005JanFeb2.pdf*

[32] *https://www.radiologybusiness.com/topics/care-delivery/rsna-2017-overuse-stat-designation-slows-mri-workflow-causes-confusion*

[33] Raskin D, Hoffmann C, Twig G, Konen E, et al. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduction of Mortality.

[34] Maya M et al. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduced Length of Stay. Cedars Sinai Medical Center, abstract submitted to RSNA 2020.

[35] Raskin D, Hoffmann C, Twig G, Konen E, et al. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduction of Mortality.

[36] Bader AS. ''Artificial Intelligence software for flagging Pulmonary Embolism on CTPA is associated with a reduced Time to Anticoagulation and reduced Hospital Length of Stay.'' Unpublished manuscript submitted for publication.

[37] Maya M et al. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduced Length of Stay. Cedars Sinai Medical Center, abstract submitted to RSNA 2020.

mutations, such as exon 20 insertion mutations, do not respond well to small-molecule, oral EGFR inhibitors or to chemotherapy. The applicant stated exon 20 insertion mutations are the most frequently observed atypical EGFR mutations affecting 4 to 10 percent of NSCLC patients with an EGFR mutation, but there are no FDA approved targeted therapies for NSCLC patients with exon 20 insertion mutations.

With respect to the newness criterion, the applicant stated that, in March 2020, RYBREVANT™ (also known as JNJ–61186372) received Breakthrough Therapy designation from the FDA for the treatment of patients with metastatic NSCLC with EGFR exon 20 insertion mutation whose disease has progressed on or after platinum-based chemotherapy. RYBREVANT™ was approved by the FDA on May 21, 2021, for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. The applicant submitted a request for a unique ICD–10–PCS procedure code to identify use of the technology and was granted approval for the following procedure codes effective October 1, 2021: XW033B7 (Introduction of amivantamab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 7) and XW043B7 (Introduction of amivantamab monoclonal antibody into central vein, percutaneous approach, new technology group 7).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that the mechanism of action of RYBREVANT™ for treating NSCLC is unique as amivantamab is anticipated to be the first FDA-approved bispecific antibody therapy targeting EGFR and MET mutations simultaneously. The applicant asserted that both EGFR and MET are involved in NSCLC pathogenesis, progression, and development of resistance to other therapies. According to the applicant, the most common first-line treatment for atypical EGFR-positive patients due to exon 20 insertion mutations is platinum-based chemotherapy. Per the applicant, there is no standard of care after progression for second-line treatment, and patients receive a variety of therapies such as chemotherapy, immunotherapy, and tyrosine kinase inhibitors, as well as combinations of these therapies. The applicant reiterated that none of these treatments are FDA approved for this patient population and that they are associated with limited efficacy for these patients.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that the use of amivantamab is not expected to affect the DRG assignment. In their cost analysis, as shown below, the applicant identified several MS–DRGs relevant to this technology.

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MS-DRG	MS-DRG Description	Cases	Percentage of Cases
871	Septicemia Or Severe Sepsis w/o Mv >96 Hours w MCC	46	13.18%
180	Respiratory Neoplasms w MCC	26	7.45%
164	Major Chest Procedures w CC	17	4.87%
193	Simple Pneumonia & Pleurisy w MCC	14	4.01%
181	Respiratory Neoplasms w CC	12	3.44%
	All Other	234	67.05%
Total		**349**	**100.00%**

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or a similar type of disease and the same or similar patient population, the applicant stated that RYBREVANT™ treats a distinct patient population with metastatic NSCLC: Metastatic NSCLC with exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. Per the applicant, there were no FDA-approved therapies at the time of the proposed rule for this patient population, and the most commonly used therapies are associated with limited efficacy.

In summary, the applicant asserted that RYBREVANT™ should be considered new and not substantially similar to an existing technology because the mechanism of action of RYBREVANT™ for treating NSCLC is unique and it treats a distinct patient population.

We invited public comments on whether RYBREVANT™ is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

Comment: The applicant submitted a comment reiterating that RYBREVANT™ meets the newness criterion because it does not meet two of the substantial similarity criteria. The applicant stated that it does not meet the first criterion because RYBREVANT™'s mechanism of action for treating NSCLC is unique in that it is the first FDA-approved bispecific antibody therapy targeting EGFR and MET mutations simultaneously, and it does not meet the third criterion since it treats a distinct patient population with metastatic NSCLC with exon 20 insertion mutations for which there is no other FDA-approved therapy.

Response: We thank the applicant for their comment. Based on this comment and on information submitted by the applicant as part of its FY 2022 new technology add-on payment application for RYBREVANT™, as discussed in the proposed rule (86 FR 25222 through 25227) and previously summarized, we believe that RYBREVANT™ has a unique mechanism of action due to treating NSCLC via bispecific antibody therapy targeting EGFR and MET mutations simultaneously. We also agree that RYBREVANT™ treats a new patient population, as there are no other FDA-approved therapies for patients

with metastatic NSCLC with exon 20 insertion mutations. Therefore, we believe RYBREVANT™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence when RYBREVANT™ was approved by FDA for the indication of treatment of advanced or metastatic NSCLC with EGFR Exon 20 insertion mutations, on May 21, 2021.

With regard to the cost criterion, the applicant provided the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched the FY 2019 Medicare Provider Analysis and Review (MedPAR) final rule file for cases based on the presence of one of the following ICD–10–CM diagnosis codes for lung cancer:

Code	Code Descriptor
C34	Malignant neoplasm of bronchus and lung
C34.0	Malignant neoplasm of main bronchus
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.1	Malignant neoplasm of upper lobe, bronchus or lung
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.3	Malignant neoplasm of lower lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	Malignant neoplasm of overlapping sites of bronchus and lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.9	Malignant neoplasm of unspecified part of bronchus or lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

We note that the applicant also provided the following ICD–10–PCS procedure codes, which the applicant stated could be used to identify cases involving RYBREVANT™ in the absence of a unique ICD–10–PCS code.

Code	Code Descriptor
3E03005	Introduction of other antineoplastic into peripheral vein, open approach
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04005	Introduction of other antineoplastic into central vein, open approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

To further refine the cases used in the analysis, the applicant used the following methodology. Per the applicant, clinical data suggests 80 to 85 percent of lung cancer patients are NSCLC patients.[38] The applicant stated that, of those patients, 10–15 percent are EGFR-mutations patients,[39] [40] and of those, at least 9 percent have atypical EGFR mutations like exon 20 ins.[41] The applicant selected 0.93% (82.5% * 12.5% * 9%) of the cases identified based on the lung cancer diagnosis codes listed previously. The applicant stated this is the target population for RYBREVANT™, which the applicant used for the cost analysis.

The applicant then accounted for the circumstances where RYBREVANT™ would be administered during an inpatient stay. The applicant stated that RYBREVANT™ will typically be administered in the outpatient setting, and that it assumed that RYBREVANT™ would be administered during an inpatient stay, possibly for care unrelated to a patient's cancer treatment, when that stay coincided with the 2-week cycle during which a patient receiving RYBREVANT™ would undergo an infusion in the outpatient setting were it not for their inpatient admission. The applicant stated that, because it is very important that patients receive continuity of cancer care, it assumed that some patients would receive their RYBREVANT™ infusion during their hospital stay. To account for this scenario, the applicant calculated the average length of stay for all of the cases in its patient population, which it asserted was about 5.862 days. The applicant then divided the average length of stay for all of the cases by 14, as per the applicant RYBREVANT™ is administered on 28-day cycle, with a weekly administration for the first cycle, and an administration every 2 weeks thereafter.

The applicant stated that current clinical guidelines are expected to give medical professionals discretion to administer RYBREVANT™ during the hospitalization or pause the treatment cycle. To account for physician discretion, the applicant included only 50 percent of these cases in the final cost analysis.

The applicant identified 349 cases mapping to the following MS–DRGs. The applicant has not made a request for RYBREVANT™ to map to a new or different MS–DRG for FY 2022.

MS-DRG	MS-DRG Description	Cases
871	Septicemia Or Severe Sepsis w/o Mv >96 Hours w MCC	46
180	Respiratory Neoplasms w MCC	26
164	Major Chest Procedures w CC	17
193	Simple Pneumonia & Pleurisy w MCCW Mcc	14
181	Respiratory Neoplasms w CC	12
	All Other	234
Total		**349**

[38] "What is Lung Cancer?" American Cancer Society. 1 October 2019: *https://www.cancer.org/content/cancer/en/cancer/lung-cancer/about/what-is.html.*

[39] Wee, P., & Wang, Z. (2017). Epidermal growth factor receptor cell proliferation signaling pathways. *Cancers,* 9(5), 52.

[40] Pao, W., & Girard, N. (2011). New driver mutations in non-small-cell lung cancer. *The Lancet Oncology,* 12(2), 175–180.

[41] Arcila, M. E., Nafa, K., Chaft, J. E., Rekhtman, N., Lau, C., Reva, B. A., and Ladanyi, M. (2013). EGFR exon 20 insertion mutations in lung adenocarcinomas: prevalence, molecular heterogeneity, and clinicopathologic characteristics. *Molecular Cancer Therapeutics,* 12(2), 220–229.

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The applicant assumed patients receiving RYBREVANT™ would receive one dose of the drug during their inpatient stay. Because RYBREVANT™ would be administered in addition to any other drugs the patient was receiving during their inpatient admission, the applicant did not remove costs associated with any previous technology. The applicant then standardized the charges using the FY 2019 IPPS/LTCH PPS final rule Impact file. Then the applicant applied the 2-year inflation factor of 13.2 percent (1.13218) from the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039). The applicant then added charges for RYBREVANT™, which the applicant determined using the inverse of the FY 2021 IPPS/LTCH PPS final rule pharmacy national average cost to charge ratio (CCR) of 0.187 (85 FR 58601).

Because the applicant calculated a final inflated average case-weighted standardized charge per case of $108,159, which exceeds the case weighted threshold of $64,736, the applicant maintained the technology meets the cost criterion.

Based on the information provided by the applicant, we stated in the proposed rule that we had several concerns with regard to whether the technology meets the cost criterion. In its cost analysis, the applicant combined 234 cases from multiple MS–DRGs into one group with a case-weight of 67 percent of cases. We stated that we do not believe this is appropriate for the cost analysis. As reflected in § 412.87(b)(3), where cases eligible for a particular technology may be assigned to multiple MS–DRGs, in performing the cost analysis, the applicant should compare the charges of the cases to a threshold amount that is the lesser of 75 percent of the standardized amount or 75 percent of one standard deviation beyond the case-weighted average of all MS–DRGs to which the cases map. In the event that a single MS–DRG has fewer than 11 cases, the applicant should impute a minimum case number of 11 rather than the actual value. In this way, the appropriate threshold and case weighted threshold value can be calculated.

In its analysis, the applicant appeared to take a sample of a larger case population based on clinical data. We stated that it was unclear whether the applicant was taking a simple random sample or a targeted sample of cases. We noted that, if the applicant obtained a random sample, this sample may not be any more representative of the larger population of cases identified by the lung cancer diagnosis codes listed previously. If the applicant instead non-randomly sampled cases from the larger population, we stated that we would like to understand the process used by the applicant to identify this targeted sample. We requested information under either approach on how a sampling of cases from the greater population is more representative of potential RYBREVANT™ patients.

We invited public comments on whether RYBREVANT™ meets the cost criterion.

Comment: The applicant provided clarifications to their analysis. With respect to the concern that the applicant combined cases from multiple MS–DRGs into one group with a case weight of 67 percent, the applicant was in agreement that it is not appropriate to combine cases that fall below the 11-case blinding threshold. The applicant stated that, in response to CMS' concern, they provided two versions of the table—one in the application pdf file with MS–DRGs that had fewer than 11 cases grouped into an ''all other'' category—and the full Excel file showing the complete list of DRGs, even if they had fewer than 11 cases.

With respect to CMS' request for information on how a random sampling of cases from the greater population is more representative of potential RYBREVANT™ patients, the applicant first reiterated the assumptions behind its original cost analysis. The applicant pointed to clinical data from the American Cancer Society suggesting 80 to 85 percent of lung cancer patients are NSCLC patients, and that of those patients, 10–15 percent are EGFR-mutations, and of those, at least 9 percent are atypical EGFR mutations like exon 20 insertions which per the applicant is the target patient population for RYBREVANT™. The applicant also stated its assumption that, although RYBREVANT™ will typically be administered in the outpatient setting, there would be situations in which the patient would be admitted to the hospital for care that is possibly unrelated to their cancer treatment, and that this inpatient stay would coincide with the day that they would normally receive RYBREVANT™ as part of their ongoing cancer treatment. Per the applicant, RYBREVANT™'s dosing regimen would mean that many beneficiaries' inpatient stays would not coincide with the RYBREVANT™ treatment scenario, and that to account for this scenario, the applicant calculated the average length of stay for all of the cases in its patient population and divided the average length of stay for all of the cases by 14, after which the applicant multiplied this new factor by the number of cases in the sample to reduce the sample to those cases where the RYBREVANT™ treatment day would occur during the hospitalization. The applicant then reiterated the clinical guidelines that give physicians discretion to administer RYBREVANT™ during the hospitalization or a pause in the treatment cycle, and stated that to account for this discretion, it included only half of these cases in its cost analysis. Per the applicant, these calculations are intended to acknowledge that while there are many patients with lung cancer diagnoses receiving different types of treatment in the hospital, there are only a small number of beneficiaries who have ESCLC and are receiving RYBREVANT™ that happen to be in the hospital on the day when they are normally scheduled to receive RYBREVANT™ whose physician would like to continue treatment during the hospitalization.

The applicant then addressed CMS' concerns by presenting a revised analysis including only the cases with the lowest total charges at each of its filtering points, rather than selecting a random sample. The applicant explained that the cases with the lowest total charges are the least likely to meet the cost criterion threshold, and so selecting those cases represented the most conservative option in selecting a sample. The applicant first reran the analysis selecting 0.93 percent of cases with the lowest total charges to account for the portion of lung cancer patients who have NSCLC and atypical EGFR mutations. The applicant further filtered the cases to account for the patients who would receive RYBREVANT™ in the hospital based on timing and physician discretion, resulting in a sample of 91 cases which the applicant reiterated had the lowest total charges. The applicant then added charges for RYBREVANT™ based on the drug's WAC, resulting in a final inflated case-weighted standardized charge per case that exceeded the case weighted threshold, and the applicant maintained that RYBREVANT™ meets the cost criterion.

Response: We thank the applicant for its comments addressing our concerns regarding the cost criterion. We appreciate the explanation of the sampling methodology behind the applicant's original analysis as well as its revised analysis representing the most conservative approach using cases with the lowest total charges that are least likely to meet the cost criterion. We agree that the applicant's approach

to sampling is reasonable and representative of potential RYBREVANT™ patients and that RYBREVANT™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that RYBREVANT™ represents a substantial clinical improvement over existing technologies. The applicant asserted several claims of substantial clinical improvement for RYBREVANT™: (1) RYBREVANT™ is anticipated to be the first therapy to treat the metastatic NSCLC with exon 20 insertion mutations for patients whose disease has progressed on or after platinum-based chemotherapy; (2) the objective response rate (ORR) was higher than what would be expected with chemotherapy or immunotherapy; (3) a clinical benefit rate higher than what would be expected with chemotherapy or immunotherapy; (4) a duration of response higher than what would be expected with chemotherapy or immunotherapy; (5) the median progression free survival was higher than what would be expected with chemotherapy or immunotherapy; and (6) the incidence and severity of diarrhea was lower than what would be expected with any oral EGFR inhibitor.

The applicant stated that patients with NSCLC and EGFR exon 20 insertion mutations have a form of disease that is generally insensitive to available EGFR TKI treatments and, as a result, carries a worse prognosis compared to patients with more common EGFR mutations.[42] Per the applicant, the current standard of care for the initial treatment of exon 20 insertion metastatic NSCLC is platinum-based chemotherapy;[43] and, after a patient with EGFR exon 20 insertion metastatic NSCLC disease progresses on or during platinum-based chemotherapy, there is no standard of care. The applicant stated there are currently no FDA-approved targeted therapies for patients with lung cancer who have EGFR exon 20 insertion mutations.[44] The applicant cited an analysis of the Flatiron Health database, which includes electronic health data records from over 265 cancer clinics representing over 2 million active US cancer patients, that found prescribers use a wide variety of treatment strategies, all of which have an unclear role in the second-line treatment of exon 20 insertion mutated metastatic NSCLC or are known to be ineffective and/or have potential tolerability issues.[45] Specifically, the analysis showed that in the second-line treatment of exon 20 insertion metastatic NSCLC, approximately 33 percent of patients received single-agent immunotherapy, 14.1 percent received an EGFR-targeting oral agent, 5.9 percent received chemoimmunotherapy combination, 5.9 percent received chemotherapy with a VEGF inhibitor, 5.9 percent received a clinical study drug, and the remainder received a variety of single-agent chemotherapies or other regimens. The applicant stated this re-iterates the lack of an accepted standard of care for the second-line treatment of exon 20 insertion metastatic NSCLC and thus underscores the unmet need of these patients. The applicant stated in their application that based on the Breakthrough Therapy designation for RYBREVANT™, it was anticipated that RYBREVANT™'s first expected approval would be for the second-line treatment of exon 20 insertion metastatic NSCLC.

The applicant provided three references to support a finding of substantial clinical improvement for RYBREVANT™ as well as some supplementary information in the application itself. The first reference was a conference presentation given at the 2019 Annual Meeting of the Society for Clinical Oncology titled ''JNJ–61186372 (JNJ–372), an EGFR-cMet bispecific antibody, in EGFR-driven advanced non-small cell lung cancer (NSCLC)'' by Haura et al. The second was a poster presented at the 2020 Annual Meeting of the American Society for Clinical Oncology titled ''Amivantamab (JNJ–61186372), an anti-EGFR–MET bispecific antibody, in patients with EGFR Exon 20 insertion (Exon20ins)-mutated non-small cell lung cancer (NSCLC)'' by Park et al. The third was a conference presentation given in January 2021 at the World Conference on Lung Cancer titled ''Amivantamab in Post-platinum EGFR Exon 20 Insertion Mutant Non-small Cell Lung Cancer'' by Sabari et al.

These three references all describe the ongoing Phase 1 trial titled ''A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ–61186372, a Human Bispecific EGFR and cMet Antibody, in Subjects With Advanced Non-Small Cell Lung Cancer'' (*https://clinicaltrials.gov/ct2/show/NCT02609776*). This open label, multicenter, first-in-human study, also known as ''CHRYSALIS,'' consists of two parts.[46] Part 1 was a dose escalation study used to establish the recommended Phase 2 dosing regimen.[47] Part 2 was a dose expansion study to assess safety and efficacy at the recommended Phase 2 dosing regimen.[48] The primary efficacy endpoint was the overall response rate per Response Evaluation Criteria in Solid Tumors v1.1.[49] Key secondary endpoints included clinical benefit rate (CBR), duration of response (DOR), progression-free survival (PFS), and overall survival (OS).[50]

Key eligibility criteria for the post-platinum population of patients enrolled in the study included: Metastatic/unresectable NSCLC, EGFR exon 20 insertion mutation, and progression on platinum-based chemotherapy.[51] Patients received the recommended Phase 2 dose of 1050 mg (1400 mg for patients ≥80 kg) amivantamab intravenously once weekly for the first cycle and biweekly thereafter.[52] The safety population (N=114) included all post-platinum exon 20 ins patients who received amivantamab at the recommended Phase 2 dose, and the response-evaluable population (n=81) included post-platinum exon 20 ins patients who had at least three disease assessments or had discontinued, progressed, or died prior to the third post-baseline assessment at the time of clinical cut-off.[53]

In the efficacy population, the median age was 62.[54] In addition, 59 percent of the patients were female, 49 percent of the patients were Asian, and 47 percent had a history of smoking.[55] Median time from initial diagnosis was 17 months

[42] Vyse, S., and Huang, P. H. (2019). Targeting EGFR exon 20 insertion mutations in non-small cell lung cancer. *Signal Transduction and Targeted Therapy,* 4(1), 1–10.

[43] Chantharasamee, J., Poungvarin, N., Danchaivijitr, P., and Techawatanawanna, S. (2019). Clinical outcome of treatment of metastatic non-small cell lung cancer in patients harboring uncommon EGFR mutation. *BMC Cancer,* 19(1), 701.

[44] Yasuda, H., Kobayashi, S., and Costa, D. B. (2012). EGFR exon 20 insertion mutations in non-small-cell lung cancer: preclinical data and clinical implications. *The Lancet Oncology,* 13(1), e23–e31.

[45] Flatiron Health database, Second Line Treatment Regimens in Advanced NSCLC (January 2015–October 2019).

[46] *https://clinicaltrials.gov/ct2/show/study/NCT02609776 https://clinicaltrials.gov/ct2/show/study/NCT02609776.*

[47] Sabari JK, Shu CA, Park K, et al. Amivantamab in post-platinum EGFR exon 20 insertion mutant non-small cell lung cancer. Oral presentation presented at: International Association for the Study of Lung Cancer (IASLC) 2020 World Conference on Lung Cancer Singapore (WCLC 2020); January 28–31, 2021; Worldwide Virtual Event.

[48] Ibid.

[49] Ibid.

[50] Ibid.

[51] Ibid.

[52] Ibid.

[53] Ibid.

[54] Ibid.

[55] Ibid.

with a range of 1–130 months.[56] All patients, by definition, had a prior history of platinum-based chemotherapy while 46 percent had prior immuno-oncology therapy and 25 percent had a history of EGFR TKI treatment.[57]

In the safety population, 98 percent of patients experienced a treatment-related adverse event.[58] Of these, 16 percent were Grade 3 or higher, 9 percent were serious, 4 percent led to discontinuation, 13 percent led to dose reduction, and 21 percent led to dose interruption.[59] Of note, 2 percent discontinued due to rash and 10 percent had treatment-related diarrhea with 8.5 percent at grade 1–2 and 3.5 percent at grade 3.[60]

The applicant stated that preliminary safety results from the CHRYSALIS trial presented at the 2020 ASCO meeting appear to demonstrate that amivantamab has a manageable safety profile, with 60% of adverse events at grade 1 to 2.[61] Per the applicant, this appears to be an improvement relative to the types and frequency of adverse events reported for platinum based chemotherapies overall in advanced NSCLC, with over half of patients reporting adverse events of grade 3 to 5, such as neutropenia, nausea, and vomiting.[62] The applicant noted the best tolerated EGFR-targeting oral agent osimertinib was associated with a rate of discontinuation due to adverse events of 13 percent in the phase 3 FLAURA study.[63] In addition, the applicant noted osimertinib was associated with a rate of any grade diarrhea of 58 percent with 2 percent of patients having grade 3 or higher in this study.[64] In the same phase 3 FLAURA study, the applicant noted the comparator arm (gefitinib or erlotinib) was associated with a 57 percent incidence of any grade diarrhea with 2 percent of patients experiencing grade 3 or higher.

Regarding efficacy, in the Sabari et al reference, a blinded independent central review found an ORR in the efficacy population of 40 percent (95 percent CI 29–51) and a median DOR of 11.1 months (95 percent CI 6.9-not reached).[65] Patients experienced a complete response in 4 percent of cases, partial response in 36 percent of cases, stable disease in 48 percent of cases, progressive disease in 10 percent of cases, and one percent of patients was not evaluable.[66] Finally, the CBR (defined as complete response, partial response, or stable disease for at least two disease assessments) was 74 percent (95 percent CI 63–83).[67] The median patient follow-up in this most recent analysis was 9.7 months (range 1.1–29.3). Of note, 47 percent of patients remained on treatment at time of data cutoff and 63 percent had responses of at least six months.[68] The median PFS was 8.3 months (95 percent CI 6.5–10.9), and the median overall survival was 22.8 months (95 percent CI 14.6-not reached).[69]

The applicant stated that, while direct comparison between therapies cannot be definitively made in the absence of comparative trials, amivantamab results appear promising and numerically better than those expected with current therapies (chemotherapy, immunotherapy, chemoimmunotherapy combination, or oral EGFR tyrosine kinase inhibitors) based on available data. The applicant stated platinum-based chemotherapy has been associated with a median progression free survival of 5.1 to 6.0 months in patients with exon 20 T790m mutations—the most common mutation observed following resistance to small molecule TKI inhibitors commonly used in advanced EGFR mutation positive NSCLC.[70] The applicant stated that oral EGFR tyrosine kinase inhibitors (for example, erlotinib, gefitinib, afatinib, dacomitinib, osimertinib) and immunotherapies are also used to treat patients with exon 20 insertion metastatic NSCLC but generally have limited efficacy as exon 20 insertion mutations have been associated with resistance to EGFR tyrosine kinase inhibitors.[71] The applicant stated most immunotherapy and chemoimmunotherapy studies have excluded patients with EGFR mutation because single-agent immunotherapies have very limited efficacy in patients with EGFR-mutated NSCLC.

The applicant provided the following table 1, which outlines median progression free survival (mPFS) and response rate (ORR) data among patients with exon 20 insertion mutation for amivantamab and some of the currently existing therapies. The applicant noted this table is intended to provide general information about individual therapies and is not intended for making direct comparisons between therapies as differences between study populations, follow-up time, prior treatments, and other factors may exist.

	Chemotherapy	Afatinib	Osimertinib	Erlotinib/Gefitinib	Amivantamab
mPFS	5.7 months	2.7 months	3.7 months	< 3 months	8.6 months
ORR	29%	9%	6%	8% - 27%	41%

Sources: Exon 20 - Chemotherapy: Zhao et al. WCLC 2018; Afatinib: Yang et al. Lancet Oncol. 2015; Osimertinib: de Langen et al. WCLC 2018; Erlotinib/Gefitinb: Vyse et al. STTT 2019; Amivantamab: Park et al. ASCO 2020.

[56] Ibid.

[57] Ibid.

[58] Ibid.

[59] Ibid.

[60] Ibid.

[61] 2020 ASCO Annual Meeting: Park, K, et al. J Clin Oncol 38:2020 (suppl; abstr 9512).

[62] Schiller, JH et al. (2002). Comparison of four chemotherapy regimens for advanced non-small-cell lung cancer. *New England Journal of Medicine,* 346(2), 92–98.

[63] Ibid.

[64] Ibid.

[65] Sabari JK, Shu CA, Park K, et al. Amivantamab in post-platinum EGFR exon 20 insertion mutant non-small cell lung cancer. Oral presentation presented at: International Association for the Study of Lung Cancer (IASLC) 2020 World Conference on Lung Cancer Singapore (WCLC 2020); January 28–31, 2021; Worldwide Virtual Event.

[66] Ibid.

[67] Ibid.

[68] Ibid.

[69] Ibid.

[70] Yoshida, T., Kuroda, H., Oya, Y., Shimizu, J., Horio, Y., Sakao, Y., et al. . . . and Yatabe, Y. (2017). Clinical outcomes of platinum-based chemotherapy according to T790M mutation status in EGFR-positive non-small cell lung cancer patients after initial EGFR–TKI failure. Lung Cancer, 109, 89–91.

[71] Vyse, S., & Huang, P.H. (2019). Targeting EGFR exon 20 insertion mutations in non-small cell lung cancer. *Signal Transduction and Targeted Therapy,* 4(1), 1–10.

Finally, the applicant cited an analysis presented at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting, which found patients experienced a median ORR of 13% and PFS of 3.5 months when receiving a wide variety of different therapies, including immunotherapies, chemoimmunotherapies, EGFR-targeting TKIs, and other chemotherapy regimens as second-line treatment.[72]

In the proposed rule, after review of the information provided by the applicant, we noted the following concerns regarding whether the technology meets the substantial clinical improvement criterion. We stated that at the time, results provided by the applicant were based on an ongoing Phase 1 trial. We were concerned that these are potentially partial results, from which end conclusions may not be drawn, and also about the potential for overestimating treatment effects when trials stop early or report interim results. We further noted that the only study cited by the applicant to establish substantial clinical improvement is a single-armed study assessing the safety and efficacy of RYBREVANT™ in the target population. As noted by the applicant, no formal comparisons to other therapies were made. Without the ability to control for factors such as study design, patient characteristics, etc., we noted that we may be unable to determine whether any differences seen are the result of RYBREVANT™'s potentially superior efficacy or confounding variables. We also noted that the single-arm study design results in an inability to distinguish between the effect of RYBREVANT™ treatment, a placebo effect, and the effect of natural course of the disease.

We invited public comments on whether RYBREVANT™ meets the substantial clinical improvement criterion.

Comment: The applicant submitted a comment regarding substantial clinical improvement. With regard to the concern that results provided by the applicant are based on an ongoing Phase 1 trial from which end conclusions may not be drawn, the applicant stated that these results supported the accelerated approval granted to RYBREVANT™ by the US FDA on May 21, 2021.[73] [74] [75] The applicant also reiterated that RYBREVANT™ received Priority Review and Breakthrough Therapy designation, and explained that these designations are significant because they are only granted to applications for drugs that would be significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions when compared to standard applications (in the case of Priority Review) or drugs that are intended to treat a serious condition and whose preliminary clinical evidence demonstrated substantial improvement over available therapy on clinically significant endpoints (in the case of Breakthrough Therapy). Per the applicant, the study that supported approval, CHRYSALIS (NCT02609776), is an ongoing, phase 1 multi-cohort, multi-center study that has not been stopped prematurely. The applicant noted that although enrollment has been closed for the study, patients continue to be followed for efficacy and safety for final data that will be provided to FDA when available. The applicant also noted that RYBREVANT™ received FDA approval based on overall response rate (ORR) and duration of response (DoR) which were assessed and confirmed by blinded independent central review (BICR) in CHRYSALIS. The applicant emphasized that there were no currently approved therapies for the target patient population with high unmet medical needs.[76] [77]

The applicant also acknowledged that continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials (RYBREVANT™ Prescribing Information). Per the applicant, the confirmatory phase 3 trial, which is currently enrolling, is a study of RYBREVANT™ in combination with platinum-based chemotherapy, compared to platinum-based chemotherapy alone in participants with advanced or metastatic NSCLC characterized by EGFR Exon 20 insertions.[78]

With respect to the concern that CHRYSALIS is a single-armed study assessing the safety and efficacy of RYBREVANT™ in the target patient population, the applicant stated that because there is no standard of care (SOC) therapy and no randomized, comparative (head-to-head) studies published in patients with NSCLC and EGFR exon 20 insertion mutations, no formal comparisons to existing treatments can be made. The applicant stated that external controls can add valuable context in interpreting RYBREVANT™ efficacy and appreciating unmet needs with current real-world therapies, the most common of which are single-agent chemotherapies, immuno-oncology therapies, and EGFR tyrosine kinase inhibitors (TKIs). Per the applicant, an external control arm was constructed using three real world datasets from US companies. The datasets were de-duplicated and adjusted using propensity score weighting for differences in age, brain metastases, ECOG PS, and prior lines of therapy. The applicant stated that patients receiving RYBREVANT™ had longer OS and PFS than patients treated with real world therapies in the post-platinum-based chemotherapy setting based on a recent analysis. Specifically, the overall response rate (ORR) was 40 percent among RYBREVANT™-treated patients, 13 to 18 percent among external controls, and 16 percent for the pooled real-world dataset. The applicant also noted that RYBREVANT™-treated patients had a 53 percent risk reduction in progression, a 60 percent risk reduction in commencement of next therapy, and a 51 percent risk reduction in death compared to external controls. Per the applicant, poor performance of the external controls reflects the ineffectiveness of currently available real world treatments and highlights the urgent need to find more targeted treatments for the patient population.[79]

[72] Park, K. (2020, May). Amivantamab (JNJ–61186372), an anti-EGFR–MET bispecific antibody, in patients with EGFR Exon 20 insertion (Exon20ins)-mutated non-small cell lung cancer (NSCLC). Poster presented at the 2020 Annual Meeting of the American Society of Clinical Oncology.

[73] PR Newswire. FDA approves first targeted therapy for subset of non-small cell lung cancer; *https://www.prnewswire.com/news-releases/fda-approves-first-targeted-therapy-for-subset-of-non-small-cell-lung-cancer-301296998.html*. May 21, 2021. Accessed June 1, 2021.

[74] Janssen Announces U.S. FDA Breakthrough Therapy Designation Granted for JNJ–6372 for the Treatment of Non-Small Cell Lung Cancer. *https://www.jnj.com/janssen-announces-u-s-fda-breakthrough-therapy-designationgranted-for-jnj-6372-for-the-treatment-of-non-small-cell-lung-cancer*. May 21, 2021. Accessed June 01, 2021.

[75] RYBREVANT (amivantamab-vmjw) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; *https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/RYBREVANT-pi.pdf*.

[76] Ibid. PR Newswire

[77] Ibid. Janssen Announces US FDA Breakthrough Therapy Designation Granted.

[78] Janssen Research & Development, LLC. A study of combination amivantamab and carboplatin-pemetrexed therapy, compared with carboplatin-pemetrexed, in participants with advanced or metastatic NSCLC characterized by EGFR Exon 20 insertions. In: *ClinicalTrials.gov* [internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2021 June 01]. Available from: *https://clinicaltrials.gov/ct2/show/NCT04538664*. NLM Identifier: NCT04538664.

[79] Minchom AR, et al. Amivantamab compared with real world therapies in patients with NSCLC with EGFR Exon 20 insertion mutations who have progressed after platinum doublet chemotherapy. Poster presented at: 2021 American Society of Clinical Oncology (ASCO) Annual Meeting; June 4–8, 2021; Virtual. Abstract 9052.

In response to our concern that the single-arm CHRYSALIS study results in an inability to distinguish between the effect of RYBREVANT™ treatment, a placebo effect, and the effect of natural course of the disease, the applicant provided a poster of results to distinguish between the effects of RYBREVANT™ treatment. The applicant stated that the poster revealed that most Exon 20 insertion mutations in NSCLC have been associated with insensitivity or resistance to currently available small-molecule TKIs and are associated with poor prognosis (93% increased risk of progression or death with EGFR Exon20ins compared to common EGFR mutations); therefore, this represents an area of high unmet medical need.[80] [81] [82] [83] The applicant stated that the 5-year relative survival rate for patients with lung and bronchus cancer is 20.5%, with rates varying by stage from 59% with localized disease to 6% with metastatic disease.[84] In addition, the 5-year relative survival rate for patients with NSCLC is 24.9%, with rates varying by stage from 63% to 7% for localized and metastatic disease, respectively.[85] The applicant further stated that a retrospective cohort study of real-world data from the Flatiron Health Database (1 January 2011 through 21 May 2020) found that patients with metastatic NSCLC harboring exon 20 insertion mutations have an estimated 5-year survival of 8% compared to 19% for patients with common EGFR mutations.[86] For these reasons, the applicant asserts that RYBREVANT™ demonstrates substantial clinical improvement for this population of patients.

Response: We appreciate the additional information provided by the applicant in response to our concerns regarding substantial clinical improvement. After reviewing the information submitted by the applicant addressing our concerns raised in the proposed rule, we agree with the applicant that RYBREVANT™ represents a substantial clinical improvement over existing technologies because, based on the information provided by the applicant, the technology offers a treatment option for patients with metastatic NSCLC with exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy, for which it is the first and only FDA approved treatment.

After consideration of the public comments we received, we have determined that RYBREVANT™ meets all of the criteria for approval for new technology add-on payments. Therefore, we are approving new technology add-on payments for RYBREVANT™ for FY 2022. Cases involving the use of RYBREVANT™ that are eligible for new technology add-on payments will be identified by ICD–10– PCS procedure codes XW033B7 (Introduction of amivantamab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 7) or XW043B7 (Introduction of amivantamab monoclonal antibody into central vein, percutaneous approach, new technology group 7).

RYBREVANT™ is administered in 26 treatments annually and is estimated that the annual cost of the product will be $180,000 per patient. In its application, the applicant stated that RYBREVANT™ is administered on a 28-day cycle. It is administered weekly for the first cycle, and every 2 weeks thereafter. The dose is 1050 mg (3 vials) for patients who weigh less than 80 kg and 1400 mg (4 vials) for patients who weigh 80 kg or more. Per the applicant, the WAC of RYBREVANT™ is $2,986.43 for a 350mL vial. According to the applicant, 70% of patients with exon 20 mutations weigh less than or equal to 80 Kg, while 30% exceed 80 kg. Therefore, the average cost per patient for RYBREVANT™ is $9,855.22 ($2,986.43 per vial * 3 vials * 0.70) + ($2,986.43 per vial * 4 vials * 0.30). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the costs of the new medical service or technology, or 65 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, the maximum new technology add-on payment for a case involving the use of RYBREVANT™ is $6,405.89 for FY 2022.

c. BREYANZI® (lisocabtagene maraleucel)

Juno Therapeutics, a Bristol-Myers Squibb Company, submitted an application for new technology add-on payment for FY 2022 for BREYANZI®. BREYANZI® is a CD19-directed, autologous chimeric antigen receptor (CAR) T-cell immunotherapy that is comprised of individually formulated CD8 (killer) and CD4 (helper) CAR T-cells indicated for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after at least two prior therapies. We note that Juno Therapeutics previously submitted an application for new technology add-on payments for BREYANZI® for FY 2021, as summarized in the FY 2021 IPPS/LTCH PPS proposed rule, under the name lisocabtagene maraleucel (85 FR 32647–32652).

According to the National Comprehensive Cancer Network, Diffuse Large B-cell lymphoma (DLBCL) is the most common type of Non-Hodgkin's Lymphoma (NHL) in the U.S. and worldwide, accounting for nearly 30% of newly diagnosed cases of B-cell NHL in U.S.[87] DLBCL is characterized by spreading of B-cells through the body that have either arrived de novo or by the transformation from indolent lymphoma.

According to the applicant, the standard-of-care, first-line immune-chemotherapy for DLBCL includes regimens such as cyclophosphamide, doxorubicin, vincristine, and prednisone plus rituximab (R–CHOP).[88] These regimens result in long-lasting remission in more than 50% of patients.[89] However, approximately 10% to 15% of patients will have primary refractory disease (that is, nonresponse or relapse within 3 months of first-line therapy), and an additional 20% to 25% will relapse following an initial response to therapy.[90] Patients with relapses of aggressive B-cell lymphomas are believed to have a poor

[72] Arcila ME, et al. ECGR exon 20 insertion mutations in lung adrenocarcinomas: Prevalence, molecular heterogeneity, and clincopathologic characteristics. Mol Cancer Ther. 2013;12(2):220–229.

[81] Yasuda H, et al. Structural, biochemical and clinical characterization of epidermal growth factor receptor (EGFR) exon 20 insertion mutations in lung cancer. *Sci Transl Med*. 2013;5(216):216ra177

[82] Yun J, et al. Antitumor activity of amivantamab (JNJ–61186372), an EGFR-cMet bispecific antibody, in diverse models of EGFR Exon 20 insertion-driven NSCLC. *Cancer Discov*. 2020;10(8):1194–1209.

[83] Girard N, et al. Comparative clinical outcomes for patients with NSCLC harboring EGFR exon 20 insertion mutations and common EGFR mutations. Oral presentation presented at: International Association for the Study of Lung Cancer (IASLC) 2020 World Conference on Lung Cancer Singapore (WCLC 2020); January 28–31, 2021; Worldwide Virtual Event.

[84] National Cancer Institute Surveillance, Epidemiology, and End Results Program (NCI SEER). Cancer stat facts: lung and bronchus cancer. 2020a. Available at: *https://seer.cancer.gov/statfacts/html/lungb.html*. Accessed June 01, 2021.

[85] National Cancer Institute Surveillance, Epidemiology, and End Results Program (NCI SEER). Cancer statistics review, 1975–2017; Table 15.14. April 15, 2020b. Available at: *https://seer.cancer.gov/csr/1975_2017/*. Accessed June 01, 2021.

[86] Ibid. Girard.

[87] Ferlay J, Colombet M, Soerjomataram, et al., Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods, Int J Cancer. 144: 1941–1953 (Ferlay, 2019); NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V. 5.2019. © National Comprehensive Cancer Network, Inc. 2019 (NCCN, 2019).

[88] Coiffier, BBertrand et al., Long-term outcome of patients in the LNH–98.5 trial, the first randomized study comparing rituximab-CHOP to standard CHOP chemotherapy in DLBCL patients: A study by Group d'Etudes des Lymphomes de l'Adulte, blood 2010 116: 2040–2045. (Coiffier, 2010).

[89] *Ibid.*

[90] Ibid.

prognosis because of potential treatment resistance and rapid tumor growth, with only about 30% to 40% responding to salvage chemotherapy (for example, R–ICE, DHAP, or Gem-ox) followed by high-dose therapy and autologous stem cell transplantation for patients demonstrating chemotherapy-sensitive disease.[91] [92] Among patients eligible to undergo autologous stem cell transplantation (ASCT), only 50% will achieve a remission adequate to proceed to ASCT, and approximately 50% will relapse after transplantation.[93] The applicant also noted that transplant eligibility is also restricted based on age and tolerance to high dose chemotherapy and thus excludes a moderate subset of patients with r/r DLBCL.

Additionally, the applicant explained that the available therapies for 3L+ large B-cell lymphoma include the following:

- CD19-directed genetically modified autologous CAR T-cell immunotherapy axicabtagene ciloleucel (YESCARTA®), approved in October 2017 for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL).[94]
- CAR T-cell therapy tisagenlecluecel (KYMRIAH®), approved in May 2018, for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from FL.[95]
- Programmed death receptor-1 (PD–1)-blocking antibody (KEYTRUDA®), approved in 2018, for the treatment of adult and pediatric patients with refractory primary mediastinal B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy.[96]
- CD79b-directed antibody-drug conjugate polatuzumab vedotin (POLIVY®), in combination with bendamustine and rituximab, approved in 2019, for the treatment of adult patients with r/r DLBCL, not otherwise specified, after at least two prior therapies.

According to the applicant, despite the availability of these therapies, r/r large B-cell lymphoma remains a major cause of morbidity and mortality due to the aggressive disease course. The applicant noted that the safety profiles of these therapies exclude many r/r large B-cell lymphoma patients from being able to undergo treatment with these therapies.[97]

With respect to the newness criterion, the applicant submitted a BLA for BREYANZI® in October 2019, and was approved by FDA on February 5, 2021. BREYANZI® was granted Breakthrough Therapy Designation (BTD) on December 15, 2016 and Regenerative Medicine Advanced Therapy (RMAT) designation on October 20, 2017, for the treatment of patients with r/r aggressive large B-cell NHL, including DLBCL, not otherwise specified (DLBCL NOS; de novo or transformed from indolent lymphoma), primary mediastinal B-cell lymphoma (PMBCL), or follicular lymphoma Grade 3B (FL3B)). BREYANZI® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. BREYANZI® is not indicated for the treatment of patients with primary central nervous system lymphoma. We note that effective October 1, 2021 the following ICD–10–PCS codes may be used to uniquely describe procedures involving the infusion of BREYANZI®: XW033N7 (Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) and XW043N7 (Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7). The applicant also submitted a request for a new HCPCS code, which will uniquely describe procedures involving the use of BREYANZI®. The applicant noted in their application that BREYANZI® would likely map to the same MS–DRG as other CAR T-cell therapies, MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy).

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant described two ways in which it believes the mechanism of action for BREYANZI® differs from previously approved therapies for DLBCL. First, the applicant described the therapy as being comprised of individually formulated cryopreserved patient-specific helper (CD4) and killer (CD8) CAR T-cells in suspension that are administered as a defined composition of CAR-positive viable T-cells (from individually formulated CD8 and CD4 components). The applicant stated that the therapy involves a different mechanism of action from other CAR–T cell therapies because the CD4 and CD8 T-cells are purified and cultured separately to maintain compositional control of each cell type. Furthermore, during culture, each cell type is separately modified to have the CAR on the cell surface, expanded and quantified, and frozen in two separate cell suspensions. The applicant then described how BREYANZI® is infused with the same target dose of CD4 and CD8 CAR T-cells for every patient. The applicant asserted that because BREYANZI® controls the same dosage for both CD4 and CD8, it differs from other CAR T-cell therapies for DLBCL and could potentially provide for higher safety and efficacy; the applicant stated that CAR T-cell therapies that do not control for CD8 CAR T-cell dosage have demonstrated higher rates of severe and life-threatening toxicities, such as cytokine release syndrome (CRS) and neurotoxicity (NT).

The second feature the applicant described as distinguishing BREYANZI®'s mechanism of action from existing CD19-directed CAR T-cell therapies was the presence of an EGFRt cell surface tag. The applicant explained

[91] Crump M, Neelapu SS, Farooq U, et al., Outcomes in refractory diffuse large B-cell lymphoma: Results from the international SCHOLAR–1 study, Blood. 2017; 130(16): 1800–1808 (Crump, 2017).

[92] Cunningham D, Hawkes EA, Jack A, et al. Rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisolone in patients with newly diagnosed diffuse large B-cell non-Hodgkin lymphoma: A phase 3 comparison of dose intensification with 14-day versus 21-day cycles Lancet. 2013; 381: 1817–1826 (Cunningham, 2013).

[93] *Ibid*.

[94] YESCARTA®'s approval was based on a single arm study (ZUMA–1) demonstrating an IRC-assessed ORR of 72%, CR of 51%, and an estimated median DOR of 9.2 months in 101 subjects included in the modified intent-to-treat (mITT population).

[95] KYMRIAH®'s approval was based on a single-arm study (JULIET) demonstrating an ORR of 50% and a CR rate of 32% in 68 efficacy-evaluable subjects. A median DOR was not reached with a median follow-up of 9.4 months.

[96] KEYTRUDA is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy. Keytruda USPI (2019).

[97] Smith SD, Reddy P, Sokolova A, et al., Eligibility for CAR T-cell therapy: An analysis of selection criteria and survival outcomes in chemorefractory DLBCL, Am. J. Hematol. 2019; E119: 1–4 (Smith, 2019).

that the EGFRt cell surface tag could hypothetically be targeted for CAR T-cell clearance by separately administering cetuximab, a monoclonal antibody. According to the applicant, if the patient was separately administered cetuximab, the presence of the EGFRt cell surface tag within BREYANZI® would allow cetuximab to bind to the CAR T-cells and clear the cells from the patient. The applicant highlighted studies that showed that persistent functional CD19-directed CAR T-cells in patients caused sustained depletion of a patient's normal B-cells that expressed CD19, resulting in hypogammaglobulinemia and an increased risk of life-threatening or chronic infections.[98] The applicant further explained that such prolonged low levels of normal B-cells could place a patient at risk of life-threatening or chronic infections. According to the applicant, the ability to deplete CAR T-cells, via the administration of cetuximab, when a patient achieves a long-term remission could hypothetically allow recovery of normal B-cells and potentially reduce the risk of life-threatening or chronic infections. The applicant noted that experiments in a laboratory setting showed that targeting EGFRt with the monoclonal antibody cetuximab eliminated CAR T-cells expressing the EGFRt marker, which resulted in long-term reversal of B-cell aplasia in mice.[99] However, the applicant noted that this mechanism of CAR T-cell clearance, via administration of cetuximab and EGFRt cell surface tags/markers, has not been tested in humans, including patients treated with BREYANZI®.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant acknowledged that the ICD–10–PCS procedure codes used to uniquely identify procedures involving the administration of BREYANZI® XW033N7 (Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) and XW043N7 (Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7) are assigned to MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy). The applicant has not made a request for the technology to map to a new or different MS–DRG for FY 2022.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, BREYANZI® fills an unmet need in the treatment of large B-cell lymphoma because BREYANZI® would be indicated as a third-line treatment option for patients with r/r DLBCL, who cannot be treated with existing CAR T-cell therapies. The applicant asserted that BREYANZI® would be able to treat these patients that present with uncommon subtypes of DLBCL including, PMBCL, FL3B, and DLBCL transformed from indolent lymphoma from other follicular lymphoma, elderly patients (≥65 years old), patients with secondary CNS involvement by lymphoma, and those with moderate renal or cardiac comorbidities. The applicant asserted that these patient populations were excluded from registrational trials for YESCARTA® and KYMRIAH®, and therefore represent an unmet patient need.

Regarding newness, we stated in the proposed rule that we were concerned whether a differing production and/or dosage represented a different mechanism of action as compared to previously FDA-approved CAR T-cell therapies. We were also concerned about whether the existence of an EGFRt cell surface tag equates to a new mechanism of action given that in order to activate this cell surface tag, an additional medication, cetuximab, which targets the CAR T-cells for clearance, would be needed. We also expressed concern that, based on our understanding, the presence of the EGFRt cell surface tag is a potential way to treat an adverse event of the BREYANZI® therapy and is not critical to the way the drug treats the underlying disease. We noted that the applicant referenced that while this EGFRt cell surface tag is included within the BREYANZI® compound, it remains dormant without activation by cetuximab. Finally, the applicant noted that BREYANZI® has been shown safe and effective for patient populations excluded from registrational trials for YESCARTA® and KYMRIAH®, including patients with uncommon subtypes of large B-cell lymphoma, including PMBCL, FL3B, and DLBCL transformed from indolent lymphoma other than FL, elderly patients (≥65 years old), patients with secondary CNS involvement by lymphoma and those with moderate renal or cardiac comorbidities.[100] We noted that the FDA label for YESCARTA® and KYMRIAH® does not appear to specifically exclude these patient populations or NHL subtypes. As such, it was unclear whether BREYANZI® would in fact treat a patient population different from other CAR T-cell therapies that treat patients with DLBCL.

We invited public comments on whether BREYANZI® is substantially similar to other technologies and whether BREYANZI® meets the newness criterion.

Comment: A commenter, the manufacturer of a competitor CAR T-cell product to BREYANZI®, stated that despite small differences in production and dosage, they agree with CMS that BREYANZI®'s mechanism of action does not represent a different mechanism of action as compared to KYMRIAH® and YESCARTA®. The commenter next provided the FDA-approved prescribing information for BREYANZI®, KYMRIAH®, and YESCARTA® which they asserted describe the same or similar mechanism of action for these technologies. The commenter added BREYANZI®, KYMRIAH®, and YESCARTA® are all CD19-directed genetically modified autologous T-cell immunotherapies that bind to CD19-expressing cancer cells and normal B cells. The commenter next stated that according to the applicant, BREYANZI®'s mechanism of action can be distinguished from existing CD19-directed CAR T-cell therapies given the presence of an EGFRt cell surface tag. According to the commenter, the applicant noted that EGFRt cell surface tag could ''hypothetically'' be targeted for CAR T-cell clearance by separately administering cetuximab, a monoclonal antibody. The commenter asserted that nevertheless, there is only preclinical murine data to support the claim that the presence of an EGFRt cell surface tag for BREYANZI® improves safety or efficacy. Therefore, the commenter asserted that the claim about the mechanism of action made by the applicant is merely hypothetical and should not be the basis to evaluate a claim for newness under the new technology add-on payment criteria. Lastly, the commenter stated that according to the applicant, BREYANZI® controls the same dosage for both CD4 and CD8, which ''could potentially provide for higher safety and efficacy'' than previously FDA-approved CAR T-

[98] Kalos M, Levine BL, Porter DL, et al., T Cells with Chimeric Antigen Receptors Have Potent Antitumor Effects and Can Establish Memory in Patients with Advanced Leukemia, Sci Transl Med. 2011; 3(95): 1–21 (Kalos, 2011).

[99] Paszkiewicz PJ, Frable SP, Srivastava S, et al., Targeted antibody-mediated depletion of murine CD19 CAR T cells permanently reverses B cell aplasia, J Clin Invest. 2016; 126(11): 4262–4272 (Paszkiewicz, 2016).

[100] Lisocabtagene maraleucel Biologics License Application (BLA).

cell therapies. In response, the commenter described an analysis of how different product attributes of KYMRIAH®, including CD4:CD8 ratio, affect efficacy and safety, in which the investigators found that the CD4:CD8 ratio had no significant impact on response rate, CRS, or neurotoxicity.[101] The commenter added that in the phase 2 trial for YESCARTA®, investigators also found that response rates did not appear to be influenced by product characteristics, including the CD4:CD8 ratio.[102]

Next, the commenter asserted BREYANZI® treats the same or similar type of disease and patient populations as KYMRIAH® and YESCARTA®. The commenter stated its disagreement that BREYANZI® presents a new treatment option for patients with r/r DLBCL that cannot be treated with existing FDA-approved CAR T-cell therapies. The commenter stated there is large overlap in the eligible patient populations for all three therapies as the patient populations or NHL subtypes are not excluded from the FDA label of the existing FDA-approved CAR T-cell therapies.

Response: We appreciate the information provided by the commenter and have taken this comment into consideration in our determination of the newness criterion.

Comment: In response to CMS' concerns in the proposed rule, a commenter stated their agreement and support that BREYANZI® needs additional data to show that it meets the newness criterion to support an approval for new technology add-on payment. The commenter stated specifically that they do not believe BREYANZI® is significantly different from the current two FDA approved CAR T-cell products YESCARTA® and KYMRIAH® for the treatment of Diffuse Large B-cell lymphoma (DLBCL). The commenter added that there have not been any head-to-head clinical trials performed to support the request from the manufacturer of BREYANZI®.

A few commenters encouraged CMS to consider assigning new technology add-on payments for new CAR T-cell therapies including lisocabtagene maraleucel to ensure patient access.

Response: We appreciate the information submitted by the commenters and have taken this into consideration in our final determination of new technology add-on payment status.

Comment: In response to CMS' concerns in the proposed rule, the applicant submitted a comment. The applicant stated that BREYANZI® does not use the same or similar mechanism of action to achieve a therapeutic outcome. The applicant asserted that in terms of the CAR construct and design, the therapy is impacted by differences in length of the transmembrane/hinge region, domain type, and costimulatory/activation domains. According to the applicant, new data demonstrates that the length of the transmembrane/hinge region, along with the domain type (CD28, CD8, etc.) in combination with the costimulatory/activation domains (CD28, 4–1BB, etc.), can affect cytokine production, proliferation, and T-cell memory generation, which are critical to the activity of CAR T-cell therapy.[103] According to the applicant, BREYANZI® utilizes a different mechanism of action from other CAR T-cell therapies, including KYMRIAH® and YESCARTA®, which are also indicated to treat certain patient populations with DLBCL. The applicant added that BREYANZI® has a unique mechanism of action because it is comprised of two individually formulated cryopreserved patient-specific helper (CD4) and killer (CD8) CAR T-cells in suspensions administered as a defined composition of CAR-positive viable T-cells in a 1:1 ratio (CD4/CD8) as compared to KYMRIAH® and YESCARTA® which are comprised of varying CD4/CD8 CAR T-cell ratios and are manufactured as mixed populations. The applicant further asserted that BREYANZI® also has the unique attribute of incorporating an EGFRt cell surface tag that could potentially be used in combination with cetuximab to eliminate the genetically altered T-cells through antibody dependent cell-mediated cytotoxicity should the patient experience a catastrophic adverse event, as compared to KYMRIAH® and YESCARTA, neither of which has this same EGFRt cell surface tag.

The applicant stated that BREYANZI® does not involve the treatment of the same or similar type of disease or same or similar patient population as other technologies. The applicant asserted BREYANZI® has been shown to be safe and effective for patient populations excluded from registrational trials for YESCARTA® and KYMRIAH®, including patients with uncommon subtypes of large B-cell lymphoma, including refractory primary mediastinal B-cell lymphoma (PMBCL), FL3B, and DLBCL transformed from indolent lymphoma other than follicular lymphoma (FL), elderly patients (≥65 years old), patients with secondary central nervous system (CNS) involvement by lymphoma and those with moderate renal or cardiac comorbidities. The applicant added the FDA labels for YESCARTA® and KYMRIAH® may not exclude all these B cell lymphoma subtypes; however, clinical studies for YESCARTA® and KYMRIAH® failed to include patients transformed from indolent lymphomas (for example, chronic lymphocytic leukemia (CLL) and marginal zone lymphoma (MZL)) and patients with FL3b. Additionally, according to the applicant, clinical studies for YESCARTA® and KYMRIAH® did not allow enrollment of patients with prior allogeneic hematopoietic stem cell transplant (HSCT) or with secondary CNS disease, reduced renal function, and other specific comorbidities. The applicant asserted its belief that it would be unlikely for a clinician to prescribe KYMRIAH® or YESCARTA® for patients that were expressly excluded from the clinical trials for those therapies and even more unlikely for a commercial payor to reimburse for the use of KYMRIAH® or YESCARTA® in a patient population that was excluded from the clinical trials. Lastly, the applicant asserted patients with FL3b are excluded from Medicare coverage for KYMRIAH® and YESCARTA® under National Coverage Determination (NCD) 110.24 (Chimeric Antigen Receptor (CAR) T cell Therapy), but are covered for BREYANZI®.[104]

Response: We appreciate the information submitted by the commenters in response to whether BREYANZI® meets the newness criterion. In regard to the first criterion, whether a technology uses the same or similar mechanism of action to achieve a therapeutic outcome, we do not believe there is a clear differentiation between the mechanism of action of BREYANZI® and currently available

[101] Backanova V, Tam CS, Borchmann P, et al. Impact of Tisagenlecleucel Chimeric Antigen Receptor (CAR)-T Cell Therapy Product Attributes on Clinical Outcomes in Adults with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (r/r DLBCL). Oral presentation presented at: 61st ASH Annual Meeting; December 7–10, 2019; Orlando, FL; Abstract 242.

[102] Neelapu SS, Locke FL, Bartlett NL, et al. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. N Engl J Med. 2017;377(26):2531–2544. doi:10.1056/NEJMoa1707447.

[103] Brudno JN, Lam N, Vanasse, D, et al. Safety and feasibility of anti-CD19 CAR T cells with fully human binding domains in patients with B-cell lymphoma, Nature Medicine. 2020; 26:270–280; Ying Z, Huang XF, Xiang X, et al. A safe and potent anti-CD19 CAR T cell therapy, Nature Medicine. 2019; 25:947–953.

[104] CMS Manual System, Pub 100–04 Medicare Claims Processing Manual, Transmittal 10796, Change Request 12177 (May 20, 2021), available at *https://www.cms.gov/files/document/r10796cp.pdf*.

CAR T-cell therapies, namely KYMRIAH® and YESCARTA®. While the applicant highlights differences, such as the length of the transmembrane/hinge region, domain type, costimulatory/activation domains and CD4/CD8 ratios, we do not believe these meaningfully differentiate the mechanism of action of BREYANZI® from other CD–19 directed CAR T-cell therapies, which are all genetically modified autologous T-cell immunotherapies that bind to CD–19 expressing cancer cells. We refer the reader to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41287 through 41291) for a further discussion of this issue, where we determined that KYMRIAH® and YESCARTA® were substantially similar to one another based on similar concerns. We agree with the first commenter that the differences in production and dosage between BREYANZI®, YESCARTA®, and KYMRIAH® do not represent a different mechanism of action. We also agree with the first commenter that the EGFRt surface tag characteristic of BREYANZI® has not been shown to be a meaningful difference due to the experimental nature from which these results are derived.

In regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, as noted in the proposed rule, the procedure codes used to describe the administration of BREYANZI® are assigned to MS–DRG 018 with other CAR T-cell therapies.

In regard to the third criterion, whether a technology treats the same or similar type of disease and patient populations, CMS notes there is substantial overlap between the patient populations treated by BREYANZI®, YESCARTA®, and KYMRIAH®. Based on B-cell lymphoma classifications and FDA indications for adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, there appear to be only limited clinical differences between BREYANZI® and the two prior therapies. Specifically, based on coverage determinations by CMS, we believe that while YESCARTA® and KYMRIAH® treat DBLCL transformed from follicular lymphoma, BREYANZI® can also treat follicular lymphoma grade 3b that does not coexist with DLBCL.

Based on the information received to date, we believe that BREYANZI® is generally intended to treat the same or similar disease in the same or similar patient population as existing CAR T-cell technologies using the same mechanism of action as previously approved CAR T-cell therapies, that of engineered autologous cellular immunotherapy comprised of CAR T-cells that recognizes CD–19 expressing cancer cells, and mapping to the same MS–DRGs. However, because BREYANZI® can also be used to treat follicular lymphoma grade 3b that does not coexist with DLBCL, we believe that this represents a new indication for BREYANZI®. Therefore, based on the information stated previously, BREYANZI® is substantially similar to YESCARTA® and KYMRIAH® with regard to the other forms of large B-cell lymphoma listed on the indication and is therefore not new for these indications. However, BREYANZI® is considered new and not substantially similar to YESCARTA® and KYMRIAH® for the specific subpopulation of cases without DLBCL but with follicular lymphoma grade 3b.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR correction notice (December 1, 2020) data file to identify potential cases representing patients who may be eligible for treatment using BREYANZI®. The applicant identified claims that reported an ICD–10–CM diagnosis code of: C83.30 (DLBCL, unspecified site); C83.31 (DLBCL, lymph nodes of head, face and neck); C83.32 (DLBCL, intrathoracic lymph nodes); C83.33 (DLBCL, intra-abdominal lymph nodes); C83.34 (DLBCL, lymph nodes of axilla and upper limb); C83.35 (DLBCL, lymph nodes of inquinal region and lower limb); C83.36 (DLBCL, intrapelvic lymph nodes); C83.37 (DLBCL, spleen); or C83.38 (DLBCL, lymph nodes of multiple sites) in one of the first five diagnosis code positions on the claim. The applicant excluded claims if they had one or more diagnoses from the list below because these conditions would preclude use of BREYANZI®.

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ICD-10-CM Code	Code Description
C72	Malignant neoplasm of spinal cord, cranial nerves and other parts of central nervous system
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C72.2	Malignant neoplasm of olfactory nerve
C72.20	Malignant neoplasm of unspecified olfactory nerve
C72.21	Malignant neoplasm of right olfactory nerve
C72.22	Malignant neoplasm of left olfactory nerve
C72.3	Malignant neoplasm of optic nerve
C72.30	Malignant neoplasm of unspecified optic nerve
C72.31	Malignant neoplasm of right optic nerve
C72.32	Malignant neoplasm of left optic nerve
C72.4	Malignant neoplasm of acoustic nerve
C72.40	Malignant neoplasm of unspecified acoustic nerve
C72.41	Malignant neoplasm of right acoustic nerve
C72.42	Malignant neoplasm of left acoustic nerve
C72.5	Malignant neoplasm of other and unspecified cranial nerves
C72.50	Malignant neoplasm of unspecified cranial nerve
C72.59	Malignant neoplasm of other cranial nerves
C72.9	Malignant neoplasm of central nervous system, unspecified
G40-G40.919	Epilepsy and recurrent seizures
A52.17	General paresis
R47.01	Aphasia
S06-S06.9X9S	Intracranial injury

ICD-10-CM Code	Code Description
G20	Parkinson's disease
G32.81	Cerebellar ataxia in diseases classified elsewhere
G11	Hereditary ataxia
G11.0	Congenital nonprogressive ataxia
G11.1	Early-onset cerebellar ataxia
G11.2	Late-onset cerebellar ataxia
G11.3	Cerebellar ataxia with defective DNA repair
G11.4	Hereditary spastic paraplegia
G11.8	Other hereditary ataxias
G11.9	Hereditary ataxia, unspecified
I60-199	Cerebrovascular diseases
F01-F99	Mental, Behavioral and Neurodevelopmental disorders
C88	Malignant immunoproliferative diseases and certain other B-cell lymphomas
C88.0	Waldenstrom macroglobulinemia
C90	Multiple myeloma and malignant plasma cell neoplasms
C90.1	Plasma cell leukemia
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse
C90.10	Plasma cell leukemia not having achieved remission
C91	Lymphoid leukemia
C91.5	Adult T-cell lymphoma/leukemia (HTLV-1-associated)
D47	Other neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
E31	Polyglandular dysfunction
E31.9	Polyglandular dysfunction, unspecified
G61	Inflammatory polyneuropathy
G61.9	Inflammatory polyneuropathy, unspecified
G62	Other and unspecified polyneuropathies
G62.1	Alcoholic polyneuropathy

ICD-10-CM Code	Code Description
G62.8	Other specified polyneuropathies
G62.82	Radiation-induced polyneuropathy
G62.81	Critical illness polyneuropathy

BILLING CODE 4120–01–C

However, the applicant noted that the aforementioned C83.XX ICD–10–CM codes do not differentiate r/r patients from the broader DLBCL population. A clinical literature search completed by the applicant found that the r/r population makes up one-fourth of the DLBCL population, but since r/r patients typically have higher inpatient costs the applicant selected 19.36 percent of the cases with the highest total charges for their cost analysis. Applying the previously mentioned parameters, the applicant found a total of 991 cases mapped to 12 MS–DRGs.

The applicant stated that the use of BREYANZI®'s therapy would replace chemotherapy or other drug therapies, including other CAR T-cell therapies. Because of this, the applicant stated they removed all charges in the drug cost center since it was not possible to differentiate between different drugs on inpatient claims. The standardized charges per case were then calculated using the 2019 IPPS/LTCH PPS final rule Impact file and the 2-year inflation factor of 13.2 percent (1.3218) was applied. Finally, to determine the charges for BREYANZI®, the applicant used the inverse of a simulated alternative cost-to-charge ratio (CCR) specifically for CAR T-cell therapies to account for CAR T-cell therapies' higher costs compared to other drugs. To determine this alternative CCR for CAR T-cell therapies, the applicant referred to the FY 2021 IPPS final rule AOR/BOR file and calculated an alternative markup percentage by dividing the AOR drug charges within MS–DRG 018 by the number of cases to determine a per case drug charge. The applicant then divided the drug charges per case by $373,000, the acquisition cost of YESCARTA® and KYMRIAH®, the CAR T-cell products used in those claims, to arrive at a CCR of 0.295. The applicant noted that the cost of BREYANZI® had not yet been determined at the time of application. However, for the purposes of its cost analysis, the applicant assumed the per-patient cost to the hospital will be $373,000. Based on the FY 2021 IPPS/LTCH PPS final rule correction notice data file thresholds for FY 2022, the applicant calculated a final inflated average case-weighted standardized charge per case of $1,377,616 which exceeded the MS–DRG 018 average case-weighted threshold of $1,251,127 by $126,489. Therefore, the applicant stated that BREYANZI® met the cost criterion.

In the proposed rule, we stated that as noted in previous discussions, the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy. Therefore, with regard to the use of this data for purposes of calculating a CAR T-cell CCR, we were uncertain how representative this data is for use in the applicant's cost analyses given this potential for variability.

We also stated that we continued to be interested in public comments regarding the eligibility of CAR T-cell technologies for new technology add-on payments when assigned to MS–DRG 018. As we have noted in prior rulemaking with regard to the CAR T-cell therapies (83 FR 41172 and 85 FR 58603 through 58608), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act. We welcomed comment on this issue.

We invited public comment on whether BREYANZI® meets the cost criterion.

Comment: MedPAC's comments addressed the cost criterion in general as it relates to CAR T-cell therapies. In particular, MedPAC stated that CMS should provide a more detailed discussion of the NTAP cost criterion and whether under the current methodology a new CAR–T product priced similarly to existing CAR–T products can meet the cost criterion. MedPAC noted that at least one of the new CAR–T products may meet the NTAP cost criterion with a manufacturer price of $373,000, but that, with a price of $373,000, the new product's price would be similar to the prices of existing CAR–T products that are paid under the existing Chimeric Antigen Receptor (CAR) T-cell Immunotherapy MS–DRG (MS–DRG 018). MedPAC further noted that the possibility that a new CAR–T product with a price similar to existing CAR–T products might meet the cost criterion and qualify for additional payments (over and above what is paid for cases using other, similarly priced CAR–T products) seems inconsistent with the intent of current NTAP policy and the new CAR–T MS–DRG.

In addition, MedPAC stated that the discussion of each NTAP applicant's cost calculations in the proposed rule is not granular enough to discern the different factors that may contribute to this potential outcome, and urged CMS to provide a more detailed discussion of this issue.

MedPAC also stated that the current cost criterion provides an incentive for manufacturers and hospitals to increase their prices and charges and noted that the Commission may examine ways to improve how Medicare pays for new products to better balance manufacturer incentives to innovate with value and affordability for beneficiaries and taxpayers.

Response: We appreciate the comment from MEDPAC on this particular issue related to CAR T-cell and the cost criterion. As we stated in section II.F.1.a.(2) of the preamble of this final rule, the cost criterion is evaluated consistently with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act. Specifically, the charges of the cases involving a new medical service or technology are compared to, and must exceed, a threshold amount which is the lesser of 75 percent of the standardized amount or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS–DRG to which the new medical service or technology is assigned.

The cost criterion is based on the average charge per case including the cost of the technology which must exceed the threshold rather than just comparing the given price of a technology to the price of other similar technologies. If a technology meets all of the new technology add-on payment criteria then it will be eligible for the

add-on payment. We refer the commenter to the spreadsheet we provide with the application (on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*) which details step-by-step calculations applicants provide with regard to the cost criterion. We believe the step-by-step calculation, which we summarized previously, meets the statutory criteria and is granular with sufficient detail to determine if the average charge per case exceeds the threshold.

With regard to MedPAC's concern that the cost criterion may provide an incentive for manufacturers and hospitals to increase their prices and charges, we welcome further comments from the public and MedPAC with regard to how to examine ways to improve how Medicare pays for new products to better balance manufacturer incentives to innovate with value and affordability for beneficiaries and taxpayers.

Comment: Commenters strongly opposed that CAR T-cell therapies would be ineligible for new technology add on payments consistent with section 1886(d)(5)(K)(ix) of the Act. The commenters voiced the need for new technology add on payments CAR T-cell therapies as they believe they are underpaid and meet all the criteria (including the cost criterion) to be eligible for new technology add on payments.

Response: We thank the commenters for their comments. In this final rule we have evaluated all CAR T-cell applications based on the traditional pathway criterion newness, cost, and substantial clinical improvement criterion. We will take the comments into consideration for future rulemaking.

Comment: In response to CMS' concerns, the applicant stated in its comment that CAR T-cell therapies that meet the cost and other criteria for new technology add-on payment status should continue to be eligible for new technology add-on payment status notwithstanding the creation of MS–DRG 018. The applicant stated that there is still a need for new technology add-on payment status for new CAR T-cell therapies, like BREYANZI®, to ensure patient access. Further, the applicant stated that while the payment amount for MS–DRG 018 is certainly more aligned with CAR T-cell therapy costs generally, BREYANZI® exceeds the cost threshold for MS–DRG 018, meaning that the reimbursement rate for MS–DRG 018 is not adequate for BREYANZI®. The applicant asserted that per CMS, this is precisely the type of scenario that the new technology add-on payment is intended to address.

In response to CMS' concerns regarding the cost criterion and the variability of provider billing and charging practices for CAR T-cell therapies, the applicant stated it considered the variability of CAR T-cell charging practices when developing its cost analyses and presented options that were intended to address this variability by using more conservative assumptions than have typically been the case for other new technology add-on payment applications. The applicant stated that most new technology add-on payment applications use the national average CCR for the cost center for which the new technology belongs to inflate the acquisition cost for the new technology to charges. The applicant added that in the case of a drug or biological, this would mean that the inverse of the national average CCR for drugs would be used to convert the WAC of BREYANZI® to charges. The applicant stated that using the drug CCR in the prescribed manner would result in charges that would potentially overstate actual hospital charging practices for CAR T-cell therapies. Furthermore, the applicant noted that numerous studies on charge compression have shown that hospital charging practices tend to result in higher markup percentages for lower cost drugs and lower markup percentages for higher cost drugs. The applicant added that given that the WAC for BREYANZI® is well above the average of drugs overall, it was concerned that using the inverse of the national average drug CCR might overstate what hospitals would typically charge for BREYANZI® on inpatient claims. Therefore, the applicant calculated a CAR T-cell specific CCR based solely on the total drug charges for CAR T-cell claims.

The applicant stated that to calculate the CAR T-cell CCR, it took the total drugs charges for cases in MS–DRG 018 from the FY 2021 IPPS Final Rule After Outliers Removed/Before Outliers Removed (AOR/BOR) file ($183,433,947.58). Next the applicant divided that amount by the number of cases (145) to determine an average drug charge per case ($1,265,061.70). Next it divided that amount by $373,000, the acquisition cost of YESCARTA® and KYMRIAH®. This value represents the average mark-up percentage hospitals used to convert the cost of CAR T-cell therapies to charges on claims in FY 2019. The applicant converted this mark-up percentage to a CCR by dividing 1 by the percentage (1/3.39 = 0.295).

Ultimately, the applicant stated it recognizes CMS' concern that hospitals vary in their CAR T-cell charging practices but states that its method for calculating a CAR T-cell specific CCR is meant to address this exact concern. The applicant asserted that by focusing solely on CAR T-cell claims, it is able to capture the range of charging practices in hospitals that used a CAR T-cell therapy in a non-clinical trial case in 2019. Furthermore, the applicant stated that in addition to addressing the concerns about variability in hospital charging practices, the CAR T-cell CCR is also a more conservative assumption to use in the cost threshold analysis because it inflates CAR T-cell costs to charges at a lower percentage (339%) than if the inverse of the national average drug CCR is used (535%).

Response: In regard to whether CAR T-cell therapies would be ineligible for new technology add on payments consistent with section 1886(d)(5)(K)(ix) of the Act, in this final rule we have evaluated all CAR T-cell applications based on the traditional pathway criteria of newness, cost, and substantial clinical improvement.

We appreciate the information provided by the applicant in their comment in regard to their calculation of a CAR T-cell CCR. As we stated in section E.2.b. of this rule, we continue to believe that it is premature to make structural changes to the IPPS at this time to pay for CAR T-cell therapies (78 FR 58453). As we gain more experience paying for these therapies under the IPPS, we may consider these comments to inform future rulemaking. However, we appreciate the thoughtfulness used by the applicant to provide as clear as possible a description of CAR T-cell therapy cost calculations. We appreciate the usage of multiple cost analyses, such as varying the CCR used to inflate cost to charges, which potentially allowed for a more conservative markup. After consideration of the public comments we received and based on the information included in the applicant's new technology add-on payment application, we believe that BREYANZI® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that BREYANZI® represents a substantial clinical improvement over existing technologies because: (1) The totality of the circumstances regarding BREYANZI®'s clinical efficacy, safety, and data make clear that BREYANZI® substantially improves, relative to services or technologies previously available, the treatment of Medicare beneficiaries with R/R NHL; (2) BREYANZI® offers a

treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; (3) BREYANZI® has, overall, an improved safety profile compared to YESCARTA and KYMRIAH; (4) BREYANZI® has a comparable or superior effectiveness compared to existing therapies; and (5) BREYANZI®'s patient population in its registrational study more accurately reflects real-world NHL patients compared to the studies of currently available CAR T-cell therapies.

The applicant asserts that the totality of the clinical efficacy and safety data from the TRANSCEND NHL 001 trial, which is a prospective, single arm, multicenter study of BREYANZI® in patients with r/r aggressive B-cell NHL, and the supportive safety data from the BREYANZI® clinical studies included in their Biologics License Application (BLA) submission demonstrate that BREYANZI® has equal or better efficacy and a better safety profile in a broad R/R patient population that better approximates the real world large B-cell lymphoma patient population—a population that the applicant asserted includes NHL subtypes not studied or approved for treatment with current approved or conditionally approved agents.

The applicant shared the results of the Phase I TRANSCEND NHL 001 trial, which was a prospective, single arm, multicenter study of BREYANZI® in patients with relapsed/refractory aggressive B-cell NHL. The applicant noted that TRANSCEND NHL 001 included subjects with the average age of 63 years with 111 subjects (41%) over 65 years of age and 27 (10%) subjects older than 75 years of age. These patients also failed previous therapies. Of the total number of subjects studied (efficacy: n=256; safety: n=269), 137 subjects (51%) had DLBCL, 60 (22%) had DLBCL transformed from FL, 18 (7%) had DLBCL transformed other indolent lymphomas, 36 patients (13%) had high grade lymphoma, 15 (6%) had PMBCL and 3 (1%) had FL3B.[105] Additionally, the applicant explained that TRANSCEND NHL 001 was more inclusive, compared to the registrational trials for KYMRIAH® and YESCARTA®, of Medicare aged patients with comorbidities and NHL disease subtypes seen in the real world presentation of the disease. To support this, the applicant referenced that within this study, between 40% to 50% of subjects studied had cardiac ejection fraction, 3% had secondary CNS lymphoma, 51 patients (19%) had a creatinine clearance between 30–60 mL/min and 39 patients (14.6%) had grade ≥3 cytopenias. Furthermore, the applicant noted that 51 patients (19%) had decreased renal function and 13 patients (4.9%) had decreased cardiac function. The applicant stated that the TRANSCEND NHL 001 study showcased that the patient population treated during the study better reflected the real world large B-cell lymphoma patient population, a population that the applicant asserted included NHL subtypes not studied or approved for treatment with currently approved or conditionally approved agents, while providing similar safety and efficacy. The applicant contended that these high-unmet need large B-cell lymphoma subsets included patients with DLBCL transformed from rare indolent lymphomas other than FL, patients with FL3B, patients 65 years of age and older, as well as patients with moderate comorbidities of renal and cardiac insufficiency.

The applicant further explained that BREYANZI® provided improved effectiveness as compared to existing therapies. Patients with aggressive large B-cell NHL who have failed at least 2 prior therapies or SCT are treated with combinations of agents or monotherapy based on institutional preferences, but there is no standard of care for salvage therapies beyond first treatment therapy.[106] The applicant noted that commonly used salvage therapies (non-CAR T-cell therapies) for relapsed, large B-cell lymphoma demonstrated objective response rates (ORRs) in the range of 12% to 46% and complete response (CR) rates of 6% to 38%. Among the patients who did achieve a response, the median duration of response (DOR) ranges from approximately 6 to 17 months and median overall survival was generally less than 12 months.[107] [108] [109] [110] [111] [112] [113] Comparatively, TRANSCEND NHL 001, which provided subjects with BREYANZI®, met its primary endpoint of Independent Review Committee (IRC)-assessed ORR in adult patients with r/r large lymphoma after at least 2 prior therapies, as reported by the applicant. In the 256 efficacy evaluable patients, the ORR was 73% (95% confidence interval (CI]): 67.0% to 78.3%), and the CR rate was 53% (95% CI: 46.6% to 59.2%). With a median follow-up of 10.8 months, the median DOR per IRC assessment was 13.3 months and the median DOR for CR was not reached. By comparison, the applicant summarized that YESCARTA®, as demonstrated in the Phase I–II ZUMA–1 study (see the FY 2019 IPPS/LTCH PPS final rule 83 FR 41295 for a description of this study), had an ORR of 72.0% (95% confidence interval (CI: 62.0% to 81.0%). Also, according to the applicant, KYMRIAH®, as demonstrated by the Phase II JULIET study (see the FY 2019 IPPS/LTCH PPS final rule 83 FR 41293 for a description of this study), had an ORR of 50.0% (95% confidence interval (CI: 38.0% to 62.0%). The applicant contended that the results for BREYANZI® (ORR of 73% (95% confidence interval (CI]): 67.0% to 78.3%), and the CR rate of 53% (95% CI: 46.6% to 59.2%)) were observed across all subgroups tested, including elderly subjects, those with high burden disease or high baseline inflammatory biomarkers, those requiring anti-lymphoma therapy for disease control, as well as rare patient populations with a high unmet medical need (for example, PMBCL, DLBCL transformed from indolent lymphoma other than FL, and FL3B). The applicant contended that this data supports that BREYANZI® demonstrates comparable or superior effectiveness compared to existing therapies for patients with r/r large B-cell NHL.[114] [115]

[105] Ibid.

[106] National Comprehensive CancerNetwork Treatment of Cancer: Guidelines, 2019. NCCN, 2019.

[107] Czuczman MS, Davies A, Linton KM, et al., A Phase 2/3 Multicenter, Randomized Study Comparing the Efficacy and Safety of Lenalidomide Versus Investigator's Choice in Relapsed/Refractory DLBCL, Blood. 2014; 124: 628 (Czuczman, 2014).

[108] Jacobsen ED, Sharman JP, Oki Y, et al., Brentuximab vedotin demonstrates objective responses in a phase 2 study of relapsed/refractory DLBCL with variable CD30 expression, Blood. 2015; 125(9): 1394–1402 (Jacobsen, 2015).

[109] Nagle SJ, Woo K, Schuster SJ, et al., Outcomes of patients with relapsed/refractory diffuse large B-cell lymphoma with progression of lymphoma after autologous stem cell transplantation in the rituximab era, Am. J. Hematol. 2013; 88: 890–894 (Nagle, 2013).

[110] Pettengell R, Coiffier B, Narayanan G, et al., Pixantrone dimaleate versus other chemotherapeutic agents as a single-agent salvage treatment in patients with relapsed or refractory aggressive non-Hodgkin lymphoma: A phase 3, multicenter, open-label, randomised trial, Lancet Oncol. 2012; 13: 696–706 (Pettengell, 2012).

[111] Rigacci L, Puccini B, Cortelazzo S, et al., Bendamustine with or without rituximab for the treatment of heavily pretreated non-Hodgkin's lymphoma patients, Ann Hematol. 2012; 91: 1013–1022 (Rigacci, 2012).

[112] Van Den Neste E, Schmitz N, Mounier N, et al., Outcome of patients with relapsed diffuse large B-cell lymphoma who fail second-line salvage regimens in the International CORAL study, Bone Marrow Transplantation. 2016; 51: 51–57 (Van Den Neste, 2016).

[113] Wang M, Fowler N, Wagner-Bartak N, et al., Oral lenalidomide with rituximab in relapsed or refractory diffuse large cell, follicular and transformed lymphoma: A phase II clinical trial, Leukemia. 2013; 27: 1902–1909 (Wang, 2013).

[114] YESCARTA® United States Prescribing Information USPI (2019).

Continued

Furthermore, the applicant stated that BREYANZI® had an improved safety profile in comparison to YESCARTA® and KYMRIAH®. The applicant stated that both of these FDA-approved CAR T-cell therapies had higher rates of toxicity as compared to BREYANZI®. In the TRANSCEND NHL 001 registrational study (n=268), 42% and 2% of subjects developed all-grade and Grade >3 CRS, respectively, and 30% and 10% developed all-grade and Grade >3 NT. The applicant compared these results to the results of the JULIET study has found in KYMRIAH's® prescribing information and summarized that KYMRIAH® had higher rates of all-grade and Grade >3 CRS (74% and 23%, respectively) and all-grade and Grade >3 NT (58% and 18%, respectively). The applicant provided the same comparison of the toxicity results of BREYANZI® to the results showcased in the ZUMA–1 study featuring YESCARTA® as found in YESCARTA®'s prescribing information and summarized that YESCARTA® had higher rates of all-grade and Grade >3 CRS (94% and 13%, respectively) and all-grade and Grade >3 NT (87% and 31%, respectively).[116] [117]

In the proposed rule, after reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application, we were concerned that there were no published studies directly comparing BREYANZI® and the two currently available CAR T-cell therapies for r/r DLBCL, YESCARTA® and KYMRIAH®. Additionally, we were concerned with the lack of long-term data supporting the effectiveness and efficacy of BREYANZI® and whether the lack of long-term data may limit the generalizability of the findings from the TRANSCEND NHL 001 study to the general Medicare population. While there have been no direct comparison studies of BREYANZI®, YESCARTA® and KYMRIAH®, the applicant did provide a comparison of the ORR, CR, PR and DOR across all three CAR T-cell therapies. While we noted that BREYANZI® does appear to provide an improved ORR, CR, PR, and DOR compared to the other FDA-approved CAR T-cell therapies based on the data presented by the applicant, we further noted that these differences appear to be small in magnitude, between 1–2% for the ORR, CR, and PR. Without a direct comparison of outcomes between these therapies, we were concerned as to whether these differences translate to clinically meaningful differences or improvements. We stated that BREYANZI® appeared to demonstrate similar patient outcomes to that of YESCARTA® and we questioned whether the TRANSCEND NHL 001 study is evidence that BREYANZI® is a more effective therapy to treat DLBCL over existing CAR T-cell therapies. Additionally, as previously discussed, the applicant noted that BREYANZI® has been shown safe and effective for patient populations excluded from registrational trials for YESCARTA® and KYMRIAH®. However, we stated it was unclear whether this suggests that BREYANZI® is a treatment option for patients who cannot be treated with these existing CART-cell therapies, given that the FDA label for YESCARTA® and KYMRIAH® appears to not specifically exclude these patient populations. Finally, we were concerned that the use of the EGFRt cell surface tag was not activated in patients receiving BREYANZI® to study the impact of clearing these CAR T-cells after remission and that this feature has not yet been tested on humans or in conjunction with patients treated with BREYANZI®. We expressed concern regarding the safety and efficacy of this feature given its lack of testing.

We invited public comments on whether BREYANZI® meets the substantial clinical improvement criterion.

Comment: In support to CMS' concerns about substantial clinical improvement, a commenter, the manufacturer of a competitor CAR T-cell product, submitted a comment. First, the commenter stated BREYANZI® is not a new treatment option for patients that can be treated by KYMRIAH® or YESCARTA®. The commenter stated that as part of the substantial clinical improvement criterion, the applicant argued that given that BREYANZI® has been shown to be safe and effective for patient populations excluded from registrational trials for KYMRIAH® and YESCARTA®, then it follows that BREYANZI® is a new treatment option for patients who cannot be treated with these therapies. The commenter was in agreement with CMS that these patient populations are not excluded from the FDA label of the existing FDA-approved CAR T-cell therapies, and thus BREYANZI® does not represent a new treatment option for these NHL subtypes.

Next, the commenter stated BREYANZI® does not demonstrate improved effectiveness over KYMRIAH® and YESCARTA®. The commenter stated that the applicant claimed that BREYANZI® demonstrated improved effectiveness as compared to existing therapies, when comparing the TRANSCEND data to that of KYMRIAH®'s JULIET trial and YESCARTA®'s ZUMA–1 trial. The commenter stated that it is not appropriate to claim clinically meaningful differences including improved effectiveness by comparing outcomes across different studies, as opposed to performing a head-to-head study, as these differences may be attributable to study populations and study design.

Lastly, the commenter stated that BREYANZI® does not demonstrate an improved safety profile over KYMRIAH® and YESCARTA®. The commenter stated that the applicant claimed that BREYANZI® demonstrates an improved safety profile in comparison to KYMRIAH® and YESCARTA®. As well as contending that it is inappropriate to claim clinically meaningful differences across different studies, the commenter stated that the safety profile between KYMRIAH® and BREYANZI® cannot be compared. However, according to the commenter, even using the applicant's own method of analysis by comparing safety data across different studies, the incidence of serious adverse reactions was in fact comparable across BREYANZI®'s TRANSCEND trial and YESCARTA®'s ZUMA–1 trial. The commenter added that the incidence of any grade neurologic events was actually lower in KYMRIAH®'s JULIET trial than in BREYANZI®'s TRANSCEND trial with a comparable incidence rate of grade ¾ neurologic events. Furthermore, the commenter stated there may also appear to be a lower incidence of Grade >3 CRS with BREYANZI® than with KYMRIAH® when looking solely at the pivotal trial data; however, this is likely due to differences in adverse event management across BREYANZI®'s TRANSCEND trial and KYMRIAH®'s JULIET trial. Lastly, the commenter stated KYMRIAH®'s safety data from the Center for International Blood and Marrow Transplant Research (CIBMTR)'s Cellular Therapy (CT) registry study [118] illustrates comparable

[115] KYMRIAH® United States Prescribing Information USPI (2018).

[116] YESCARTA® USPI (2019).

[117] KYMRIAH® USPI (2018).

[118] CIBMTR is a research collaboration between the National Marrow Donor Program® (NMDP)/Be The Match® and the Medical College of Wisconsin (MCW). The CIBMTR® CT registry study was a requirement from FDA's approval of Kymriah® and required Novartis to conduct a postmarketing, prospective, multicenter observational study to assess the long-term safety and the risk of all secondary malignancies occurring after treatment with tisagenlecleucel.

safety to the TRANSCEND trial in true real-world conditions. The commenter stated of the 155 patients with NHL evaluated in the CIBMTR CT registry study, the rate of grade 3 or higher CRS and neurotoxicity occurred in 4.5% and 5.1% of patients respectively.[119] The commenter concluded that even if safety data is compared across the different trials—which it stated is problematic—BREYANZI® is in fact not a safer therapy to treat DLBCL over existing FDA-approved CAR T-cell therapies.

Response: We appreciate the additional information submitted by the commenter and have taken this comment into consideration in determining whether BREYANZI® meets the substantial clinical improvement criterion.

Comment: The applicant submitted a comment in response to CMS' concerns on substantial clinical improvement. The applicant stated that BREYANZI® is a substantial clinical improvement over existing technologies because: (1) The totality of the circumstances regarding BREYANZI®'s clinical efficacy, safety, and data make clear that BREYANZI® substantially improves, relative to services or technologies previously available, the treatment of Medicare beneficiaries with relapsed/refractory (R/R) NHL; (2) BREYANZI® fills an unmet need among patients with R/R NHL; (3) BREYANZI® has, overall, an improved safety profile compared to YESCARTA® and KYMRIAH®; (4) BREYANZI® has a comparable or superior effectiveness compared to existing therapies; and (5) BREYANZI®'s patient population in its registrational study more accurately reflects real-world NHL patients compared to the studies of currently available CAR T-cell therapies.

According to the applicant, first, CMS questions the lack of long-term data supporting the effectiveness and efficacy of BREYANZI® and whether the lack of long-term data may limit the generalizability of the findings from the TRANSCEND NHL 001 study to the general Medicare population.[120] The applicant stated they believe this concern is unwarranted because the duration of data is unrelated to the generalizability of data to the Medicare population, the TRANSCEND NHL 001 trial was specifically designed to include a patient population that is representative of real-world Medicare beneficiaries with NHL, including comorbidities, and BREYANZI®, like the other CAR T-cell therapies, is a new technology, none of which have long-term data.

Next the applicant stated that CMS raises questions regarding the lack of published studies directly comparing BREYANZI® with YESCARTA® and KYMRIAH®.[121] The applicant stated they appreciate what they stated was CMS' recognition that BREYANZI® demonstrates improved clinical outcomes compared to KYMRIAH® and YESCARTA®, which supports that BREYANZI® is a substantial clinical improvement over prior technologies. The applicant asserted that a head-to-head comparison of the therapies is not required for purposes of new technology add-on payment status. The applicant further asserted that BREYANZI® is clearly superior to both products from a safety perspective with any grade and grade ¾ CRS rate of 42% and 2% respectively,[122] compared to 94% and 13% for YESCARTA® [123] and 57% and 17% for KYMRIAH®.[124] The applicant stated BREYANZI® showed equivalent efficacy and improved safety compared to YESCARTA®, and improved efficacy with similar safety compared with KYMRIAH®. Thus, according to the applicant, the very nature of these differences demonstrates that BREYANZI® is in fact a substantial clinical improvement.

Next the applicant stated that CMS asks whether the TRANSCEND NHL 001 study is evidence that BREYANZI® is a more effective therapy to treat DLBCL over existing CAR T-cell therapies or whether BREYANZI® has similar patient outcomes to YESCARTA®.[125] The applicant contends that BREYANZI® is an equally effective and safer CAR T-cell therapy than YESCARTA® since the TRANSCEND NHL 001 study population represents a more accurate real-world population and is more inclusive of patients across multiple large B-cell lymphoma subtypes as well as patients with comorbidities than was represented in the registrational trial for YESCARTA®. The applicant asserted that three retrospective studies suggest that restrictive eligibility criteria employed in the YESCARTA® ZUMA–1 study made for an overall study population with a more favorable prognosis and better outcomes with standard and CAR T-cell therapy.[126] [127] [128] According to the applicant, these three studies each demonstrated that patients who did not meet key eligibility criteria for ZUMA–1 were found to have a substantially shorter survival compared to those enrolled to ZUMA–1. According to the applicant, the TRANSCEND NHL 001 study included these patients. The applicant further asserted that BREYANZI® results should be more equivalent to real-world patients based on the fact that the enrolled population that was at high risk for worse outcomes compared to the population studied for YESCARTA® in ZUMA–1. Yet, despite that, according to the applicant, BREYANZI® showed equivalent efficacy and improved safety compared to YESCARTA®. The applicant stated that one can only speculate as to what the efficacy would have been for BREYANZI® had the patient population in TRANSCEND NHL 001 been limited in the same manner as the patient population for ZUMA–1.

Lastly, the applicant stated that they believe it is important to underscore that the potential use of the EGFRt cell surface tag is a method of last resort to alleviate any severe toxicities that may become life threatening to a patient. The applicant added that given the overall safety profile of BREYANZI®, it is expected that the potential use of the EGFRt cell surface tag would be extremely rare. The applicant asserted that the existence of the EGFRt cell surface tag at least provides a potential option for patients who are at serious risk of death due to a rare adverse event; according to the applicant, the lack of this option for patients treated with YESCARTA® and KYMRIAH® means that there are limited options to mitigate serious incidents.

Response: We thank the commenters for the additional information in response to our substantial clinical improvement concerns. We note that in their comment, the applicant stated that CMS recognized that BREYANZI® demonstrates improved clinical outcomes compared to KYMRIAH® and

[119] Pasquini MC, Hu ZH, Curran K, et al. Real-world evidence of tisagenlecleucel for pediatric acute lymphoblastic leukemia and non-Hodgkin lymphoma. Blood Adv. 2020;4(21):5414–5424.

[120] 86 FR at 25233.

[121] 86 FR at 25233.

[122] Abramson JS, Palomba ML, Gordon LI, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL001): a multicentre seamless design study. Lancet. 2020; 396(10254): 839–852 (Abramson, 2020).

[123] Yescarta® U.S. Prescribing Information (2020).

[124] Kymriah® U.S. Prescribing Information (2018).

[125] 86 FR at 25233.

[126] Smith SD, Reddy P, Sokolova A, et al., Eligibility for CAR T cell therapy: An analysis of selection criteria and survival outcomes in chemorefractory DLBCL, Am J Hematol. 2019; 94(4): E116–E117.

[127] Nastoupil LJ, Jain MD, Spiegel JY, et al., Axicabtagene Ciloleucel (Axi-cel) CD19 Chimeric Antigen Receptor (CAR) T cell Therapy for Relapsed/Refractory Large B-Cell Lymphoma: Real World Experience, Blood. 2018; 132:91.

[128] Jacobson CA, Hunter B., Armand P, et al., Axicabtagene Ciloleucel in the Real World: Outcomes and Predictors of Response, Resistance and Toxicity, Blood. 2018; 132: 92.

YESCARTA®, which supports that BREYANZI® is a substantial clinical improvement over prior technologies. We believe the applicant may have misunderstood what was stated in the proposed rule. Rather, we stated in the proposed rule that some data may show improvement but the differences were small and may not translate to clinically meaningful differences or improvements (86 FR 25233). We did not claim that BREYANZI® was a substantial clinical improvement. We further stated that we were not certain that the benefits were meaningful and due to differences in treatment, rather than other factors such as sample characteristics or study design. While the applicant asserts that BREYANZI® represents a substantial clinical improvement over YESCARTA® and KYMRIAH®, we continue to have concerns with regard to whether BREYANZI® demonstrates an improved safety profile compared to existing treatments as discussed by a commenter. Furthermore, as noted previously in this section, we believe BREYANZI® is generally substantially similar to YESCARTA® and KYMRIAH® and not new. Moreover, the applicant did not provide data for the specific subpopulation of patients without DLBCL and with follicular lymphoma grade 3b, for which we consider Breyanzi® new. Upon further review of the TRANSCEND NHL 001 study, three patients had FL3b at baseline.[129] While the authors report that two patients with FL3b who received Breyanzi® remained in complete response after 1 year, we are not certain that these results can be generalizable to the greater FL3b patient population. We accept all information submitted by applicants and consider it in our determination of substantial clinical improvement. However, we believe a sample size of two or three patients is a very small sample from which to generalize about a larger population to then make a determination of substantial clinical improvement.

While we believe head to head studies are ideal for demonstration of superiority and to determine a difference in treatment effects, we accept all information submitted by applicants, as stated previously. However, we believe that we are consistent in requiring that the applicant provide data designed to test differences in treatment effects to allow us to distinguish the effect of a particular treatment from the effects of study design, sample characteristics, etc.

We agree with the applicant that the generalizability of a study may not be directly related to whether a study is long-term and we appreciate the TRANSCEND NHL 001 was designed to include a patient population that is representative of real-world Medicare beneficiaries with NHL. However, we note that long-term data supports the effectiveness and efficacy of a technology, and without long-term data, it is difficult to determine if benefits seen are durable.

We also note the applicant commented that there is a potential use of the EGFRt cell surface tag to alleviate severe toxicities in patients. We appreciate that this may be a potential use, however as a commenter stated, this is only supported by preclinical murine models. Without clinical trial data, we remain concerned that we are unable to verify the applicant's claims of a potential for positive clinical outcomes related to claims made about the EGFRt cell surface tag.

Therefore, for the reasons discussed previously, particularly the insufficiency of data evaluating the population for which Breyanzi is considered new, we are unable to determine whether Breyanzi® represents a substantial clinical improvement for the specific subpopulation for which it would be eligible for new technology add-on payments. Also, as noted previously, BREYANZI® is considered not new and substantially similar to YESCARTA® and KYMRIAH® with regard to the other forms of large B-cell lymphoma listed on the indication and is therefore not new for these indications. Therefore, we are not approving new technology add-on payments for Breyanzi for FY 2022.

d. COSELA™ (trilaciclib)

G1 Therapeutics submitted an application for new technology add-on payments for Trilaciclib for FY 2022. COSELA™ (trilaciclib) is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES–SCLC).[130]

According to the applicant, COSELA™ is a first-in-class myelopreservation therapy that has the potential to mitigate chemotherapy-induced myelosuppression (CIM). COSELA™ is a selective, transient inhibitor of cyclin dependent kinases 4 and 6 (CDK4/6) with potential antineoplastic and chemoprotective activities. CDK4 and CDK6 are key regulators of the G1 cell-cycle checkpoint and play important roles in cell proliferation and associated biological processes. One of the most common pathways dysregulated in cancer is the cyclin D-cyclin-dependent kinase four or six (CDK4/6)-retinoblastoma (RB) pathway. COSELA™ arrests hematopoietic stem and progenitor (HSPCs) bone marrow cells in the G1 phase of the cell cycle during chemotherapy exposure, protecting them from chemotherapy-induced damage.

According to the applicant, the defining characteristic of cancer is uncontrolled cellular proliferation, a phenomenon that requires tumor cells to avoid or disable normal, physiologic cell-cycle regulation. While there are both CDK 4/6 independent and dependent cells, HSPCs and immune cells are CDK 4/6 dependent whereas SCLC cells are CDK 4/6 independent. According to the applicant, the transient arrest of HSPCs and lymphocytes by COSELA™ during the administration of chemotherapy is thought to have a number of beneficial effects, including a reduction in chemotherapy-induced myelosuppression and preservation of immune function, as well as an enhanced immune response.[131] [132] [133] Specifically, SCLC cells replicate independently of CDK 4/6 and therefore these cells are damaged by chemotherapy. Because HSPCs and

[129] Abramson JS, Palomba ML, Gordon LI, et al., Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicenter seamless design study. Lancet. 2020; 396(10254):839–852.

[130] G1 Therapeutics Inc., Rev. 2/2021, COSELA prescribing information: *https://www.g1therapeutics.com/cosela/pi/#:~:text=COSELA%20is%20indicated%20to%20decrease,cancer%20(ES%2DSCLC).&text=The%20recommended%20dose%20of%20COSELA%20is%20240%20mg%2Fm2%20per%20dose.*

[131] Daniel D, Kuchava V, Bondarenko I, et al. Trilaciclib (T) decreases myelosuppression in extensive-stage small cell lung cancer (ES–SCLC) patients receiving first-line chemotherapy plus atezolizumab. Ann Oncol. 2019;30:v713, Abstract 1742PD: *https://www.g1741therapeutics.com/file.cfm/1734/docs/tr-G1741_ESMO2019_Daniel.pdf.*

[132] Weiss JM, Csoszi T, Maglakelidze M, et al. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: a phase Ib/randomized phase II trial. Ann Oncol. 2019;30(10):1613–1621.

[133] Hart LL, Andric ZG, Hussein MA, et al. Effect of trilaciclib, a CDK 4/6 inhibitor, on myelosuppression in patients with previously treated extensive-stage small cell lung cancer receiving topotecan. J Clin Oncol. 2019;37(15_suppl): Abstract 8505: *https://www.g8501therapeutics.com/file.cfm/8534/docs/tr-G8501T8528-8503%8520ASCO%202019%202020Oral%202020Presentation%20060119-20060111.pdf.*

lymphocytes are CDK 4/6 dependent, COSELA™'s mechanism of action is believed to preserve these cells by temporarily arresting their proliferation during chemotherapy. In this way, COSELA™ reduces chemotherapy-induced myelosuppression in patients with extensive-stage small-cell lung cancer (ES–SCLC).[134] The applicant also asserted that in preclinical models, CDK4/6 inhibition by COSELA™ also alters the tumor immune microenvironment through transient inhibition of the immune cells known as lymphocytes that are also dependent on CDK4/6 activity for proliferation.[135]

According to the applicant, chemotherapy remains the cornerstone of treatment for extensive stage small cell lung cancer (ES–SCLC). The applicant asserted that almost all of the ~18,600 ES–SCLC patients diagnosed each year are treated with platinum/etoposide-containing or topotecan-containing chemotherapy regimens. Chemotherapy drugs target cells at different phases of the cell cycle. According to the applicant, systemic chemotherapy, alone or in combination with immune checkpoint inhibitors, is the standard of care for patients with advanced SCLC. Additionally, per the applicant, rescue interventions, including growth factors and blood transfusions, are commonly routine therapies for SCLC. The applicant also indicated that granulocyte colony-stimulating factors (G–CSFs) only address neutropenia, while erythropoiesis stimulating agent (ESAs) and red blood cell (RBC) transfusions only address anemia, and there is no available treatment that broadly mitigates myelosuppressive effects and their corresponding impact on patient well-being before chemotherapy damage occurs.

COSELA™ received FDA's New Drug Application approval on February 12, 2021. COSELA™ is for intravenous use only. The recommended dose of COSELA™ is 240 mg/m2 as a 30-minute intravenous infusion completed within four hours prior to the start of chemotherapy on each day chemotherapy is administered.[136] The applicant also stated that in 2019, COSELA™ was granted Breakthrough Therapy Designation for the mitigation of clinically significant chemotherapy-induced myelosuppression in adult patients with SCLC. The applicant submitted a request for a new ICD–10–PCS code and was granted approval for the following codes to uniquely identify COSELA™ effective October 1, 2021: XW03377 (Introduction of trilaciclib into peripheral vein, percutaneous approach, new technology group 7) and XW04377 (Introduction of trilaciclib into central vein, percutaneous approach, new technology group 7).

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that COSELA™, also referred to as G1T28, has a unique mechanism of action as a small molecule, competitive inhibitor of CDK4/6, with potential antineoplastic and chemoprotective activities. The applicant stated that upon administration, COSELA™ binds to and inhibits the activity of CDK4/6, thereby blocking the phosphorylation of the retinoblastoma protein (Rb) in early G1. This prevents G1/S phase transition, causing cell cycle arrest in the G1 phase and induced apoptosis, which inhibits the proliferation of CDK4/6-overexpressing tumor cells. In patients with CDK4/6-independent tumor cells, G1T28 may protect against multi-lineage chemotherapy-induced myelosuppression (CIM) by transiently and reversibly inducing G1 cell cycle arrest in hematopoietic stem and progenitor cells (HSPCs) and preventing transition to the S phase. Per the applicant, this protects all hematopoietic lineages, including red blood cells, platelets, neutrophils and lymphocytes, from the DNA-damaging effects of certain chemotherapeutics and preserves the function of the bone marrow and the immune system.

The applicant stated that the cell cycle consists of four distinct phases, Gap 1 phase (G_1), S phase, Gap 2 (G_2) post-synthesis phase, and the M phase.[137] Regulation of this process is maintained by a series of highly conserved proteins referred to as cyclins, and their catalytic binding partners, CDKs. The CDKs are a family of enzymes that control several cellular processes in mammalian cells, including the modulation of the cell cycle via binding to cyclins A–E, which results in the activation of transcription factors that regulate the cellular transition from G1 (growth phase) to S (DNA replication) and G2 (growth phase) to M (mitosis).[138]

According to the applicant, the G1–to–S checkpoint is a critical restriction point in the process of cell division. Cells are maintained in a quiescent state until the proper signal is achieved for reentry into the cell cycle. Throughout G1, expression of the D-type cyclins (D1, D2, D3) increases until active complexes with CDK4/6 are formed. Active CDK4/6 complexes partially phosphorylate RB, which allows partial depression of the transcription factor E2F. This induces additional transcript production of cyclin E1, which binds CDK2 to form active complexes that result in the hyperphosphorylation of RB and drives the cells through late G1 into S phase. Inhibition of cyclin D–CDK4/6 by the tumor suppressor CDKN2A leads to a G1 arrest and cell-cycle progression is halted.[139]

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserted that COSELA™ will be assigned the same MS–DRG as existing technologies. The applicant did not explicitly state to which MS–DRG(s) COSELA™ would be assigned, but included MS–DRGs 180 (Respiratory Neoplasms with MCC), 181 (Respiratory Neoplasms with CC), and 182 (Respiratory Neoplasms without CC/MCC) in its cost analysis.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that COSELA™ is the only proactive (preventive) multilineage

[134] Donjerkovic D, Scott DW. Regulation of the G1 phase of the mammalian cell cycle. *Cell Res.* 2000;10(1):1–16.

[135] Lai AY, Sorrentino JA, Dragnev KH, et al. CDK⁴⁄₆ inhibition enhances antitumor efficacy of chemotherapy and immune checkpoint inhibitor combinations in preclinical models and enhances T-cell activation in patients with SCLC receiving chemotherapy. J Immunother Cancer. 2020;0:e000847. doi:10.1136/jitc-2020–000847.

[136] G1 Therapeutics Inc., Rev. 2/2021, COSELA prescribing information: *https://www.g1therapeutics.com/cosela/pi/#:~:text=COSELA%20is%20indicated%20to%20decrease,cancer%20(ES%2DSCLC).&text=The%20recommended%20dose%20of%20COSELA%20is%20240%20mg%2Fm2%20per%20dose.*

[137] Ferrarotto R, Anderson I, Medgyasszay B, et al. Trilaciclib reduces the need for growth factors and red blood cell transfusions to manage chemotherapy-induced myelosuppression. Poster presented at: IASLC: 2020 North America Conference on Lung Cancer; October 16–17, 2020; Virtual congress.

[138] Asghar U, Witkiewicz AK, Turner NC, Knudsen ES. The history and future of targeting cyclin-dependent kinases in cancer therapy. Nat Rev Drug Discov. 2015;14(2):130–146.

[139] Donjerkovic D, Scott DW. Regulation of the G1 phase of the mammalian cell cycle. Cell Res. 2000;10(1):1–16.

(erythrocytes, leukocytes, and thrombocytes, neutrophils and lymphocytes) therapy given as a 30-minute infusion administered prior to chemotherapy on each day of chemotherapy. Due to its mechanism of action, COSELA™'s benefit is coupled to its administration schedule (that is, COSELA™ must be administered prior to chemotherapy to ensure G1 arrest of HSPCs when those cells are exposed to cytotoxic chemotherapy). According to the applicant, this therapeutic paradigm contrasts with standard available treatment options and interventions that are administered after chemotherapy to reactively reduce or treat chemotherapy side effects. The applicant asserted that typical supportive care rescue interventions such as growth factors (G–CSFs, ESAs) and red blood cell (RBC) transfusions are used after chemotherapy causes damage to stem cells. Current supportive care therapies are used reactively to treat single cell lineage specific (leukocytes and erythrocytes) complications,[140] such as neutropenia and anemia. Additionally, the applicant indicated that growth factor and RBC transfusion use are known to carry a number of risks and cause complications and adverse events.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25240), we noted that the information provided by the applicant in response to whether COSELA™ treats the same or similar type of disease or the same or similar patient population, appeared to only speak to the first criterion and whether COSELA™ has a mechanism of action that is different than existing technologies; however, we stated we believe COSELA™ appears to treat the same patient population and disease as existing therapies.

We invited public comments on whether COSELA™ is substantially similar to an existing technology and whether it meets the newness criterion.

[140] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Hematopoietic Growth Factors. Version 1.2020. 27 January. 2020.

Comment: The applicant submitted a comment reiterating that COSELA™ meets the newness criterion because it is the first and only FDA-approved therapy to provide myeloprotective efficacy. The applicant stated that existing treatments are single lineage rescue interventions and that COSELA™ is the only available treatment that broadly mitigates multilineage myelosuppressive effects and their corresponding impact on patient well-being before chemotherapy damage occurs. The applicant further explained that existing therapies, such as growth factors (granulocyte colony stimulating factor (G–CSF), erythropoiesis-stimulating agents (ESAs) and red blood cell (RBC) transfusions) do not treat chemotherapy-induced myelosuppression but that they treat the side effects of chemotherapy-induced myelosuppression, such as single cell lineage specific complications like neutropenia and anemia after chemotherapy damage has occurred. The applicant also stated that existing therapies are designed to work in different ways and treat different conditions than COSELA™.

The applicant also stated that COSELA™ does not treat the same or similar patient population as existing therapies but that it treats adult patients diagnosed with ES–SCLC prior to a platinum/etoposide-containing regimen or topotecan-containing regimen whereas the patient population treated by other therapies (for example, G–CSF, ESAs, and RBC transfusions) is patients with side effects associated with chemotherapy-induced myelosuppression. The applicant stated that COSELA™ treats a patient population that is not currently served by growth factors. The applicant concluded by reiterating that COSELA™ does not use the same mechanism of action, does not treat the same condition or disease, and does not treat the same patient population as existing therapies.

Response: We thank the applicant for its comment and the additional information submitted in regard to the newness criterion. Based on our review, we agree that COSELA™ has a unique mechanism of action to decrease the incidence of chemotherapy-induced myelosuppression in adult patients by preventing it when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for ES–SCLC. Though the applicant states that COSELA™ treats a new patient population since it treats patients before they encounter side effects from chemotherapy-induced myelosuppression, we disagree that patients with such side effects would be considered a distinct patient population because COSELA™ also treats adult patients with ES–SCLC.

Based on information submitted by the applicant in its comment and as part of its FY 2022 new technology add-on payment application for COSELA™, as discussed in the proposed rule (86 FR 25239) and previously summarized, we believe that COSELA™ has a unique mechanism of action. Therefore, COSELA™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence when COSELA™ was approved by FDA to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES–SCLC), on February 12, 2021.

With respect to the cost criterion, the applicant conducted the following analysis to demonstrate that COSELA™ meets the cost criterion. In identifying the cost of COSELA™, the applicant stated that dosing is based on body surface area, 240 mg/m^2 with an average of two vials (300mg each) per patient per dose. To identify cases that may be eligible for the use of COSELA™, the applicant searched the FY 2019 MedPAR LDS file for claims reporting an ICD–10–PCS code of category C34 through C34.92 (Malignant neoplasm related to the bronchus, lobe, or lung) as noted in the following table.

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Code	Code Descriptor
C34	Malignant neoplasm of bronchus and lung
C34.0	Malignant neoplasm of main bronchus
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.1	Malignant neoplasm of upper lobe, bronchus or lung
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.3	Malignant neoplasm of lower lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	Malignant neoplasm of overlapping sites of bronchus and lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung

Code	Code Descriptor
C34.9	Malignant neoplasm of unspecified part of bronchus or lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

According to the applicant, based on the advice of clinical experts, it limited case selection criteria to claims that included one of MS–DRGs 180, 181, or 182. The applicant then randomly selected 15% of the claims from the sample to account for the fact that SCLC comprises 15% of lung cancer cases.[141] Based on the FY 2019 MedPAR LDS file, the applicant identified 3,500 cases. The applicant noted that 2,346 cases mapped to MS–DRG 180; 1,085 cases mapped to MS–DRG 181; and 69 cases mapped to MS–DRG 182.

Using these 3,500 cases, the applicant then calculated the unstandardized average charges per case for each MS–DRG. Because the use of COSELA™ results in approximately half of patients no longer needing drugs used to counter the effects of chemotherapy during the inpatient stay, the applicant removed 50% of the drug charges for the technology being replaced.

The applicant then standardized the charges using the 2019 IPPS/LTCH PPS final rule impact file and inflated the charges by 1.13218 or 13.2 percent, the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule. The applicant then added the charges for COSELA™ by converting the costs to a charge by dividing the cost by the national average cost-to-charge ratio of 0.187 for pharmacy from the FY 2021 IPPS/LTCH PPS final rule.

Using the data file thresholds associated with the FY 2021 IPPS/LTCH PPS final rule correction notice, the average case-weighted threshold amount was $57,031. In the applicant's analysis, the final inflated average case-weighted standardized charge per case was $95,701. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

With respect to the cost criterion, we noted in the proposed rule that in listing the codes it used to identify cases that may be eligible for the use of COSELA™, the applicant provided several ICD–10 codes that lack four digits and thus, are considered invalid. We stated that we would be interested in understanding the basis for the applicant's choice of codes. We also noted that in its analysis, the applicant randomly selected 15% of the claims from the sample to account for the fact that SCLC comprises 15% of lung cancer cases. In so doing, we stated that the applicant was making the assumption that SCLC cases are randomly distributed amongst all cases from which the applicant sampled. By randomly sampling the population, the applicant was selecting a subsample that is ideally similar to the population with less variance. We stated that it may be the case that SCLC cases are systematically different from other cases in the population. If this is true, then a random sample may not be appropriate. Accordingly, we questioned the appropriateness of the sampling used and whether it accurately represents cases that would use the technology.

Finally, with respect to pricing, we stated that it appeared that the applicant's final inflated average case-weighted standardized charge per case reflected pricing prior to the availability of more current total wholesale acquisition cost. We therefore requested that the applicant update its cost analysis to reflect the final inflated average case weighted standardized charge per case based on this more current information. We invited public comment on whether COSELA™ meets the cost criterion.

Comment: The applicant submitted a comment in response to these concerns. First, with respect to the ICD–10 codes included in the application lacking four digits, the applicant stated that the codes used in the cost criterion analysis included both the two to three-digit code family names and all the four-digit codes that fall within the code families. The applicant clarified that in querying the claims data, only the codes with four digits resulted in usable claims for the analysis. The applicant clarified that the codes used to identify the claims for the cost criterion analysis were limited to the following four-digit ICD–10–CM codes:

[141] Govindan R, et al. *J Clin Oncol*. 2006;24:4539–44. Byers LA, Rudin CM. *Cancer*. 2015;121:664–72.

Code	Code Descriptor
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

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Second, with respect to whether the applicant's sampling accurately represents cases in which the technology would be used, the applicant indicated that it relied on a random sample of lung cancer cases derived by selecting 15 percent of the claims from the sample to account for the fact that SCLC comprises 15 percent of lung cancer cases, since there was a lack of evidence suggesting a more specified sample should be used instead. The applicant further stated that in further examining the claims data, the current ICD–10–CM codes do not provide the level of detail and granularity to correctly identify the SCLC population from the larger lung cancer population. The applicant also stated that without a precise mechanism to differentiate the 15 percent of cases that would be eligible for COSELA™ from the 85 percent of cases where use of COSELA™ would not be clinically appropriate, it made the best assumption based on the information available, acknowledging that the random sample collected may not be perfectly representative of the target SCLC population but, absent additional information to otherwise identify the population, a random sample was the most appropriate assumption. The applicant stated that it ran an additional, more conservative analysis using the 15 percent of lung cancer cases with the lowest total charges recognizing that that sample would be the least likely to meet the cost threshold, and that COSELA™ still met the cost criterion. The applicant concluded in noting that there is no clinical information to suggest that this sample is more representative of the COSELA™-eligible population than the random sample used in the original analysis.

Finally, with respect to pricing, the applicant submitted an updated cost analysis based on newly available total wholesale acquisition cost (WAC) of COSELA™ of $1,417 per vial. The applicant stated that an average hospitalization would include one

cycle, which is comprised of three doses. The applicant further noted that each dose includes two vials and therefore, on average, an inpatient hospitalization would involve six vials of COSELA™ for a total cost of $8,502 per hospitalization. The applicant also stated that in relying on the conservative analysis using 15 percent of lung cancer cases with the lowest charges, there is a final inflated case weighted standardized charge per case of $58,314, which exceeds the case weighted threshold of $54,566. The applicant also stated that it assumed hospitals will use the inverse of the national average cost to charge ratio for pharmacy to markup charges and therefore assumed that charges for COSELA™ would be $45,465. The applicant concluded by stating that COSELA™ meets the cost criterion because the final inflated case weighted standardized charge per case of $58,314 exceeds the case weighted threshold of $54,566.

Response: We appreciate the applicant's clarification that only the codes with four digits resulted in usable claims for the cost analysis. We also appreciate the additional information from the applicant regarding its use of a random sample for purposes of its initial analysis, as well as its supplemental cost analysis using the 15 percent of lung cancer cases with the lowest total charges. Based on the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for COSELA™, as discussed in the proposed rule (86 FR 25240 through 25242) and previously summarized, and the updated analysis provided in the applicant's public comment, we agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore,COSELA™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that trilaciclib represents a substantial clinical improvement over existing technologies because it offers a treatment option for patients unresponsive to or ineligible for currently available treatments and improves clinical outcomes for a patient population as compared to currently available treatments. The applicant stated that chemotherapy-induced myelosuppression (CIM) is typically managed with treatment dose delays and reductions due to the slow recovery of bone marrow after a course of chemotherapy.[142] The applicant also stated that CIM is managed with rescue interventions including hematopoietic growth factors (G–CSFs and ESAs) and by RBC and platelet transfusions.[143] [144] Per the applicant, despite the availability and use of these treatment options, CIM continues to be of clinical significance and remains a central concern in the delivery of chemotherapy.[145] [146] The applicant further stated that myelosuppression results in dose reductions, dose delays, and/or dose discontinuations, affecting the dose intensity and intended antitumor efficacy of chemotherapy.[147] Per the applicant, the supportive care interventions for treatment of myelosuppression are suboptimal and are often administered reactively, do not protect the bone marrow from chemotherapy-induced cytotoxic effects, are specific to single hematopoietic lineages, and impart their own risks for adverse reactions.[148] The applicant concluded by stating that new approaches that proactively prevent chemotherapy-induced damage and its associated consequences, whilst not decreasing the efficacy of chemotherapy, are urgently needed to improve care of patients with ES–SCLC.[149]

In regard to the claim that the use of COSELA™ significantly improves clinical outcomes for a patient population as compared to currently available treatments, the applicant stated that the administration of COSELA™ prior to chemotherapy in patients with SCLC prevented chemotherapy-induced neutropenia, reduced chemotherapy-induced anemia, reduced CIM or sepsis-related hospitalizations, and has the potential to improve the management and quality of life of patients receiving myelosuppressive chemotherapy as compared to placebo.[150]

The applicant presented eight claims in support of the assertion that COSELA™ represents substantial clinical improvement over existing technologies in the mitigation of clinically significant chemotherapy-induced myelosupression in adult patients with SCLC.

In its first and second claims, the applicant asserted that COSELA™ reduces the mean duration of severe G4 neutropenia in cycle 1 of chemotherapy and reduces the proportion of patients experiencing severe G4 neutropenia in comparison to placebo. The applicant submitted three sources in support of these claims. First, the applicant submitted a poster presentation from Daniel, et. al., describing a global, randomized, double-blind, placebo-controlled, multicenter, phase 2 study that assessed the potential of COSELA™ to reduce the incidence and consequences of chemotherapy-induced myelosuppression in patients with newly diagnosed ES–SCLC treated with etoposide, carboplatin, and atezolizumab. One hundred seven eligible patients were randomized to receive COSELA™ (n=53) or placebo (n=54). The primary endpoints were mean duration of severe neutropenia (SN) in cycle 1 and percent of patients with grade 4 SN. Results summarized mean duration of SN in cycle 1 as 0 days with trilaciclib and 4 days with placebo, and percent of patients with grade 4 SN as 1.9% vs 49.1%, respectively.[151]

Second, the applicant submitted an article by Weiss, et. al., summarizing a phase II randomized, double-blind placebo-controlled study of the safety, efficacy and pharmacokinetics (PK) of COSELA™ in combination with etoposide/carboplatin (E/P) therapy for treatment-naive extensive-stage small-cell lung cancer patients. Thirty-nine patients were included in the COSELA™ group versus 38 in the

[142] Crawford J, Dale DC, Lyman GH. Chemotherapy-induced neutropenia: Risks, consequences, and new directions for its management. Cancer. 2004;100(2):228.

[143] Kurtin S. Myeloid Toxicity of Cancer Treatment. *J Adv Pract Oncol* 2012;3:209–24.

[144] Asghar U, Witkiewicz AK, Turner NC, Knudsen ES. The history and future of targeting cyclin-dependent kinases in cancer therapy. Nat Rev Drug Discov. 2015;14(2):130–46.

[145] Crawford J, Dale DC, Lyman GH. Chemotherapy-induced neutropenia: Risks, consequences, and new directions for its management. Cancer. 2004;100(2):228.

[146] Lyman GH. Chemotherapy dose intensity and quality cancer care. Oncology (Williston Park). 2006;20(14 Suppl 9):16–25.

[147] Smith RE. Trends in recommendations for myelosuppressive chemotherapy for the treatment of solid tumors. J Natl Compr Canc Netw. 2006;4(7):649–58.

[148] Bisi JE, Sorrentino JA, Roberts PJ, Tavares FX, Strum JC. Preclinical characterization of G1T28: A novel CDK4/6 inhibitor for reduction of chemotherapy-induced myelosuppression. Mol Cancer Ther. 2016;15(5):783–93.

[149] Nurgali K, Jagoe T, Raquel Abalo R. Editorial: Adverse Effects of Cancer Chemotherapy: Anything New to Improve Tolerance and Reduce Sequelae? Front Pharmacol. 2018;9:245.

[150] Ferrarotto R, Anderson I, Medgyasszay B, et al. Trilaciclib reduces the need for growth factors and red blood cell transfusions to manage chemotherapy-induced myelosuppression. Poster presented at: IASLC: 2020 North America Conference on Lung Cancer; October 16–17, 2020; Virtual congress.

[151] Daniel D, Kuchava V, Bondarenko I et al. Trilaciclib Decreases Myelosuppression in Extensive-Stage Small Cell Lung Cancer (ES–SCLC) Patients Receiving First-Line Chemotherapy Plus Atezolizumab [Poster Presentation]. European Society of Medical Oncology (ESMO). October, 2019; Barcelona, Spain.

placebo group. The applicant stated that treatment with COSELA™ resulted in a reduced mean duration of severe G4 neutropenia in cycle 1 (0 days versus 3 days in placebo) and reduced proportion of patients experiencing severe G4 neutropenia for COSELA™ (5% versus 43%).[152]

Third, the applicant submitted a presentation from Hart, et. al., describing a randomized, double-blind, placebo-controlled, phase 2 study to compare the results of 32 patients receiving COSELA™ versus 28 receiving placebo in patients being treated with topotecan for previously treated ES–SCLC. Primary endpoints were mean duration of SN in cycle 1 and the percentage of patients with SN. Results demonstrated that the mean duration of severe G4 neutropenia in cycle 1 was reported at 2 days for COSELA™ versus eight days for placebo. The proportion of patients experiencing severe G4 neutropenia was reported at 41% for COSELA™ versus 76% for placebo.[153]

In the third claim, the applicant asserted that COSELA™ reduces the proportion of patients experiencing febrile neutropenia treatment emergent adverse events (TEAE) in comparison to placebo. In the fourth claim, the applicant asserted that COSELA™ decreases the rate of therapeutic intervention with G–CSF in comparison to placebo, noting that growth factors are known to carry a number of risks, cause complications and adverse events. In the fifth claim, the applicant asserted that COSELA™ reduces the proportion of patients experiencing grade 3/4 anemia in comparison to placebo. In the sixth claim, the applicant asserted that COSELA™ decreases the rate of therapeutic intervention with red blood cell transfusions in comparison to placebo. To support these claims, the applicant submitted a 2020 poster presentation from Weiss, et. al., describing a pooled analysis across three RCTs that compared the proportion of ES–SCLC patients experiencing febrile neutropenia between COSELA™ and placebo. The COSELA™ group included 122 patients and the placebo group included 118 patients. The presentation reflected the following results: The proportion of patients experiencing febrile neutropenia for COSELA™ was 3% versus placebo at 9%; the rate of therapeutic intervention with G–CSF for COSELA™ at 29% versus 56% for placebo; the proportion of patients experiencing grade 3/4 anemia for COSELA™ at 20% versus 32% for placebo; and the rate of therapeutic intervention with red blood cell transfusions for COSELA™ at 15% versus 26% for placebo.[154]

In the seventh claim, the applicant asserted that COSELA™ delays time to deterioration in symptoms and functioning domains of patient-reported quality of life measures on Functional Assessment of Cancer Therapy (FACT) scores. The applicant submitted a 2019 presentation from Weiss, et. al., describing a pooled analysis across three RCTs. The applicant stated that COSELA™ delays time to confirmed deterioration in a variety of symptoms and functioning domains compared to placebo, for example: Median of 4.7 months delay to deterioration for fatigue; median of 3.5 months delay for anemia; and median of 4 months delay for functional well-being.[155]

In the eighth claim, the applicant asserted that COSELA™ decreases the number of hospitalizations due to myelosuppression or sepsis. The applicant submitted a conference agenda referring to an oral presentation by Ferrarotto, et. al., at the North America Conference on Lung Cancer, October 16, 2020. The applicant stated that hospitalizations due to myelosuppression or sepsis occurred in significantly fewer patients and significantly less often among patients receiving COSELA™ prior to chemotherapy versus placebo though we were unable to locate support for this claim in the conference agenda submitted with the application.[156]

With respect to the substantial clinical improvement criterion, we noted several concerns in the proposed rule (86 FR 25243 through 25244). First, the data submitted by the applicant included one published peer reviewed article from Weiss, et. al.,[157] abstracts from Daniel, et. al.,[158] and Hart, et. al.,[159] and references to trials exploring broader cohorts of small cell lung cancer, breast cancer and colon cancer patients. In addition, as summarized previously, we noted that most of the studies submitted by the applicant had sample sizes fewer than 100 participants which may limit generalizability of the studies. With respect to the Weiss, et. al., study, we noted that COSELA™ was compared with placebo at a significance level of two-sided $\alpha = 0.2$ which is much lower than the typical cutoff of 0.05 and may have increased the risk of false positives and interfered with the ability to draw conclusions that are based on statistical methods. We also noted the lack of any statistical correction for multiple comparisons. We noted that in sources provided by the applicant, mean duration of severe neutropenia was assessed in day increments.[160] [161] [162] [163] However, it was

[152] Weiss JM, Csoszi T, Maglakelidze M et al. Myelopreservation with the CDK4/6 inhibitor Trilaciclib in Patients with Small-Cell Lung Cancer Receiving First-Line Chemotherapy: A Phase Ib/Randomized Phase II Trial. Ann Oncol. 2019;30(10):1613–1621.

[153] Hart LL, Andric ZG, Hussein MA et al. Effect of Trilaciclib, a CDK4/6 Inhibitor, on Myelosuppression in Patients with Previously Treated Extensive-Stage Small Cell Lung Cancer [Oral Presentation]. Presented at: American Society of Clinical Oncology (ASCO). June 2019; Chicago, US.

[154] Weiss J, Goldschmidt J, Andric Z et al. Myelopreservation and Reduced Use of Supportive Care with Trilaciclib in Patients with Small Cell Lung Cancer [Poster Presentation]. Presented at: American Society of Clinical Oncology (ASCO). May 2020.

[155] Weiss J, Skaltsa K, Gwaltney C, et al: Results from three phase 2 randomized, double-blind, placebo-controlled small cell lung cancer trials. 2019 Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology International Symposium on Supportive Care in Cancer. Abstract eP723. Presented June 21, 2019.

[156] Ferrarotto R, Anderson I, Medgyasszay B, et al. Trilaciclib reduces the need for growth factors and red blood cell transfusions to manage chemotherapy-induced myelosuppression. [Oral Presentation]. Presented at: North America Conference on Lung Cancer, October 2020. *https://naclc2020.iaslc.org/program-at-a-glance/.*

[157] Weiss JM, Csoszi T, Maglakelidze M, et al. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: A phase Ib/randomized phase II trial. Ann Oncol. 2019;30(10):1613–1621.

[158] Daniel D, Kuchava V, Bondarenko I, et al. Trilaciclib (T) decreases myelosuppression in extensive-stage small cell lung cancer (ES–SCLC) patients receiving first-line chemotherapy plus atezolizumab. Ann Oncol. 2019;30:v713, Abstract 1742PD.*https://www.g1741therapeutics.com/file.cfm/1734/docs/tr-G1741_ESMO2019_Daniel.pdf.*

[159] Hart LL, Andric ZG, Hussein MA, et al. Effect of trilaciclib, a CDK ⅘ inhibitor, on myelosuppression in patients with previously treated extensive-stage small cell lung cancer receiving topotecan. J Clin Oncol. 2019;37(15_suppl): Abstract 8505: *https://www.g8501therapeutics.com/file.cfm/8534/docs/tr-G8501T8528-8503%8520ASCO%202019%202020Oral%202020Presentation%20060119-20060111.pdf.*

[160] Weiss JM, Csoszi T, Maglakelidze M, et al. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: A phase Ib/randomized phase II trial. Ann Oncol. 2019;30(10):1613–1621.

[161] Daniel D, Kuchava V, Bondarenko I, et al. Trilaciclib (T) decreases myelosuppression in extensive-stage small cell lung cancer (ES–SCLC) patients receiving first-line chemotherapy plus atezolizumab. Ann Oncol. 2019;30:v713, Abstract 1742PD: *https://www.g1741therapeutics.com/file.cfm/1734/docs/tr-G1741_ESMO2019_Daniel.pdf.*

[162] Hart LL, Andric ZG, Hussein MA et al. Effect of Trilaciclib, a CDK4/6 Inhibitor, on Myelosuppression in Patients with Previously Treated Extensive-Stage Small Cell Lung Cancer [Oral Presentation]. Presented at: American Society of Clinical Oncology (ASCO). June 2019; Chicago, US.

[163] Weiss J, Goldschmidt J, Andric Z et al. Myelopreservation and Reduced Use of Supportive

Continued

not clear that zero days would indicate that those patients experienced no severe neutropenia. Specifically, we questioned whether mean hours in severe neutropenia was evaluated or whether, in addition to the groupings by days, one day or less would be an appropriate value for inclusion. Finally, while the applicant referred to decreases in the number of hospitalizations, we noted that the source provided was limited to a conference agenda that only linked to an abstract pertaining to reductions in utilization of supportive care interventions but did not reflect hospitalization rates.[164]

We invited public comments as to whether COSELA™ met the substantial clinical improvement criterion.

Comment: The applicant submitted comments stating that COSELA™ satisfies the substantial clinical improvement criterion. Specifically, the applicant reiterated that COSELA™ plus the standard of care demonstrated substantial clinical improvement over placebo plus the standard of care in decreasing the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for ES–SCLC. The applicant also stated that compared with placebo, COSELA™ consistently reduced the incidence and duration of chemotherapy-induced neutropenia, as measured by both the duration and occurrence of severe neutropenia. The applicant also stated that COSELA™ consistently reduced chemotherapy-induced anemia compared with placebo, reflected by the reduced occurrence of RBC transfusions on or after week 5, and a reduction in ESA use. Per the applicant, fewer patients on COSELA™ were hospitalized due to chemotherapy induced myelosuppression or sepsis and that by reducing the incidence of chemotherapy-induced myelosuppression and reducing the need for associated supportive care and hospitalizations, COSELA™ has the potential to improve the management and quality of life of patients receiving myelosuppressive chemotherapy for the treatment of ES–SCLC and is therefore a substantial clinical improvement over prior therapies.

In response to CMS' concerns with respect to the limited published studies and small sample sizes of the studies, the applicant noted that the Daniel et. al. study publication is now available and is considered its pivotal study.[165]

The applicant further noted that within the pivotal study, the planned sample size of this study was 106 (~53 per group) and was calculated to support the evaluation of COSELA™ prior to carboplatin, etoposide and atezolizumab (E/P/A) placebo prior to E/P/A on each of the primary endpoints, with at least 90 percent power at a two-sided significance level of 0.025 (Bonferroni split of overall 2-sided $\alpha = .05$ between the two primary endpoints).[166]

The applicant further stated that the pivotal study assumed treatment effects on duration of severe neutropenia (DSN) in C1 and occurrence of severe neutropenia (SN) were a between-group mean difference of 2 days (standard deviation 2.5), and an absolute reduction of 34 percent (assuming a placebo event rate of 45 percent), respectively. The applicant stated that within the pivotal study, the sample size was adjusted for the possibility that 5 percent of patients would not have any post-baseline absolute neutrophil count assessments.[167]

Next, in response to our concern regarding the low significance level cutoff of the Weiss et. al.[168] study, the applicant clarified that they viewed this study as exploratory whereas the Daniel et al.[169] study was the applicant's pivotal study. The applicant further noted that the pivotal study relied on the typical cutoff for alpha, meaning that it did not rely on significance levels as low as $\alpha = 0.2$ and thus asserted that there is less concern regarding false positive results or the ability to draw conclusions based on statistical methods.

In response to our concern related to assessing the mean duration of severe neutropenia in day increments as opposed to smaller time increments, the applicant clarified that in the pivotal study, zero days indicates that in the COSELA™ arm, there was a mean duration of zero days of severe neutropenia in cycle 1. The mean duration of severe neutropenia in cycle 1 was zero days (standard deviation 1.0) for COSELA™ vs 4 days (standard deviation 4.7) for placebo ($p < 0.0001$). The applicant also stated that a total of 1 patient (1.9%) on the COSELA™ arm experienced severe neutropenia in any cycle, whereas a total of 26 patients (49.1%) on the placebo arm experienced severe neutropenia in any cycle ($p < 0.0001$).[170]

Response: We thank the applicant for its comment and clarifications regarding the substantial clinical improvement analysis. After consideration of the public comments received, we believe that COSELA™ demonstrates a substantial clinical improvement over existing technologies in decreasing the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for ES–SCLC. We appreciate the applicant's clarification that days of severe neutropenia were evaluated by the mean number of days and not partial days and agree with the applicant that COSELA™ demonstrated superior outcomes as compared to placebo given the significant reduction in severe neutropenia and therefore believe COSELA™ offers a therapeutic option that can decrease the occurrence and duration of neutropenia. We also believe that COSELA's potential to improve quality of life by preventing the side effects of chemotherapy, as opposed to treating them once they occur, is clinically important. We note that we remain unable to confirm the assertion that COSELA™ decreases hospitalization rates as we did not receive a source to support it.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that COSELA™ meets all of the criteria for approval of the new technology add-on payment for the reasons stated previously. Therefore, we are approving

Care with Trilaciclib in Patients with Small Cell Lung Cancer [Poster Presentation]. Presented at: American Society of Clinical Oncology (ASCO). May 2020.

[164] Ferrarotto R, Anderson I, Medgyasszay B, et al. Trilaciclib reduces the need for growth factors and red blood cell transfusions to manage chemotherapy-induced myelosuppression. [Oral Presentation]. Presented at: North America Conference on Lung Cancer, October 2020. *https://naclc2020.iaslc.org/program-at-a-glance/.*

[165] Daniel D, et al. Trilaciclib prior to chemotherapy and atezolizumab in patients with newly diagnosed extensive165stage small cell lung cancer: A multicentre, randomised, double-blind, placebo-controlled Phase II trial. International Journal of Cancer. 2020: 148(10); 2557–70.

[166] Ibid.

[167] Daniel D, et al. Trilaciclib prior to chemotherapy and atezolizumab in patients with newly diagnosed extensive167stage small cell lung cancer: A multicentre, randomised, double-blind, placebo-controlled Phase II trial. International Journal of Cancer. 2020: 148(10); 2557–70.

[168] Weiss JM, Csoszi T, Maglakelidze M, et al. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: a phase Ib/randomized phase II trial. Ann Oncol. 2019;30(10):1613–1621.

[169] Daniel D, et al. Trilaciclib prior to chemotherapy and atezolizumab in patients with newly diagnosed extensive169stage small cell lung cancer: A multicentre, randomised, double-blind, placebo-controlled Phase II trial. International Journal of Cancer. 2020: 148(10); 2557–70.

[170] Ibid.

new technology add-on payments for COSELA™ for FY 2022. Cases involving the use of COSELA™ that are eligible for new technology add-on payments will be identified by ICD–10– PCS procedure codes XW03377 (Introduction of trilaciclib into peripheral vein, percutaneous approach, new technology group 7) or XW04377 (Introduction of trilaciclib into central vein, percutaneous approach, new technology group 7).

In submitting its public comment, the applicant identified the cost of COSELA™ as $8,502 per hospitalization. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of COSELA™ is $5,526.30 for FY 2022.

e. Ellipsys® Vascular Access System

Avenu Medical, Inc. submitted an application for new technology add-on payments for the Ellipsys® Vascular Access System (''Ellipsys'') for FY 2022. Ellipsys is a device that enables percutaneous creation of an arteriovenous fistula (AVF), which is used to access the bloodstream for hemodialysis for the treatment of end-stage renal disease (ESRD). According to the applicant, to create the fistula, a physician inserts a crossing needle through the perforating vein and into the proximal radial artery in the forearm. A specialized catheter is then used to bring the artery and vein together. The two vessels are ''welded'' together with thermal resistance energy, creating an anastomosis. According to the applicant, the only means of creating an AVF was through open surgery before the approval of Ellipsys, and percutaneous AVF (pAVF) offers a number of advantages over surgical AVF (sAVF).

With respect to the newness criterion, the applicant for Ellipsys received 510(k) clearance from the FDA on August 9, 2019, with an indication for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.[171] The subject of this 510(k) clearance was an update to the Instructions for Use (IFU) to allow an additional procedural step for balloon dilation of the anastomosis junction at the radial artery and adjacent outflow vein of the AVF immediately after creation with the Ellipsys catheter. Per the applicant, the device was immediately available on the market. The applicant further stated that the device was originally approved under a De Novo clearance on June 22, 2018. Ellipsys also received two additional 510(k) clearances dated January 25, 2019 (minor change in the packaging of components) and October 5, 2018 (minor technological differences in the power control unit and minor enhancements to the catheter design) but the applicant states they are not regarded as material for this application. The FDA has classified Ellipsys as a Class II device under the generic name percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access. The applicant stated that currently, two ICD–10–PCS codes identify procedures using Ellipsys: 031B3ZF (Bypass right radial artery to lower arm vein, percutaneous approach); and 031C3ZF (Bypass left radial artery to lower arm vein, percutaneous approach). However, since these codes also identify the WavelinQ™ EndoAVF System (''WavelinQ''), another percutaneous fistula device, Avenu Medical submitted a code request for a unique ICD–10–PCS code to distinctly identify Ellipsys beginning in FY 2022 and was granted approval for the following procedure codes, effective October 1, 2021: X2KB317 (Bypass right radial artery using thermal resistance energy, percutaneous approach, new technology group 7) and X2KC317 (Bypass left radial artery using thermal resistance energy, percutaneous approach, new technology group 7). The applicant stated this technology was first assigned HCPCS code C9754 on January 1, 2019, which was then replaced by HCPCS code G2170 on July 1, 2020. Per the applicant, WavelinQ was assigned HCPCS codes (C9755 replaced by G2171) with the same timing, and the codes for the 2 pAVF technologies are differentiated by the use of thermal resistance energy for Ellipsys and the use of radiofrequency energy for WavelinQ.

The applicant stated that hemodialysis access for the treatment of ESRD can be provided by catheter, graft, or AVF, of which AVF is generally preferred for patients whose vascular anatomy and condition permit it. Per the applicant, the only method for creating an AVF was through an open surgical approach until the introduction of Ellipsys and WavelinQ, two devices that use a percutaneous approach.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that Ellipsys uses a new mechanism of action compared to its initial clearance. Per the applicant, the current device included an additional step in the IFU, creating a different procedure profile and a different mechanism of action. The applicant states that the addition of this step, a balloon angioplasty performed within the same operative session as the creation of the pAVF, instead of days or weeks later, typically contributes to decreased time to maturation, improved initial flow, and helps avoid early thrombosis of the newly-created access, in addition to decreasing the number of secondary procedures required for maturation and maintenance. According to the applicant, the explicit inclusion of the step in the IFU, where it was not previously explicitly included, represents a new mechanism of action.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant generally stated that Ellipsys is assigned to the same MS–DRGs as existing technologies. According to information provided by the applicant, these MS–DRGs appear to be MS–DRGs 264, 356, 357, 358, 628, 629, 630, 673, 674, 675, 907, 908, 909, 981, 982, and 983.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant generally stated that Ellipsys will be used to treat the same or similar type of disease and the same or similar patient population as the current standard-of-care treatments.

In summary, the applicant believed that Ellipsys is not substantially similar to other currently available therapies and/or technologies because it uses a new mechanism of action and that therefore, the technology meets the ''newness'' criterion. However, in the proposed rule, we stated that we believe that the mechanism of action for Ellipsys may be the same or similar to the original version of the Ellipsys

[171] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. 510(k) Summary No. K1191114. 2019. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191114.pdf.*

system, which received FDA approval on June 22, 2018. We stated that though the current IFU includes an additional procedure as part of the index procedure, it is not clear that this step of balloon angioplasty done concurrently changes the mechanism of action of the Ellipsys system. Per the FDA's 510(k) summary, compared to the predicate device, there were no changes to the device or the manner in which it creates a percutaneous anastomosis, and other than the additional procedural step of balloon dilation, all characteristics remain unchanged.[172] In addition, we noted that clinicians were not precluded from performing this step before the change in the IFU, and in fact, balloon dilation was already performed during the index procedure in some cases.[173] Though the applicant maintained that performing this additional step in all cases, as opposed to some, leads to superior clinical outcomes, we stated that it was unclear whether this has any bearing on newness for this technology or if it represents a change in the mechanism of action of this device. We noted that if the current device is substantially similar to the original version of Ellipsys, we believe the newness period for this technology would begin on June 22, 2018 with the De Novo approval date and, therefore, because the 3-year anniversary date of the technology's entry onto the U.S. market (June 22, 2021) would occur in FY 2021, the technology would no longer be considered new and would not be eligible for new technology add-on payments for FY 2022. We welcomed public comments on whether the change in the Ellipsys IFU represents a change to the device's mechanism of action.

We also noted that differences in mechanism of action between Ellipsys and WavelinQ were not included. We noted that CMS stated in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58702) that WavelinQ uses a unique mechanism of action that differed from that of other commercially available devices.

We invited public comments on whether Ellipsys is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

Comment: We received a comment from a competitor stating that they believe that the mechanism of action for Ellipsys has not changed, and is the same as the original version approved on June 22, 2018. Per the commenter, it is still the use of thermal resistance energy that creates the fistula, as no changes were made to the predicate device for the 510(k) clearance, and though balloon angioplasty could potentially assist with maturation, it does not support the actual fistula creation. Therefore, the commenter believes the underlying mechanism of action is unchanged. The commenter further stated that since Ellipsys meets the other two criteria, as it is assigned to same MS–DRGs and treats the same disease and patient population as the earlier version of Ellipsys, and has a newness date of June 22, 2018 due to substantial similarity with the earlier version, Ellipsys should not be considered new and would not be eligible for new technology add-on payments for FY 2022.

Response: We appreciate the information provided by the commenter and have taken this comment into consideration in our determination of the newness criterion, which is described later in this section.

Comment: The applicant submitted a public comment in response to the concerns that CMS presented in the FY 2022 IPPS/LTCH PPS proposed rule regarding the newness criterion. In response to the concern that the mechanism of action of Ellipsys is unchanged from the De Novo version, the applicant stated that the additional step of immediate balloon angioplasty creates a different procedural profile, which makes a material difference not only in the procedure but in outcomes. The applicant described improvements in brachial artery flow volume in the post-market maturation study by Hull et al. described previously, which used the additional step of balloon angioplasty immediately after anastomosis creation, demonstrating a positive impact on patient care by avoiding complications that may limit use of the fistula. Per the applicant, the study demonstrated a decrease in early thrombosis, decreased time to two-needle cannulation, and decreased secondary procedures as compared to the pivotal trial where balloon angioplasty was done in only a small portion of cases. The applicant further stated that where the use of the prior version of Ellipsys might be considered to have one aspect of fistula creation, the current version might be considered to have two aspects: Fistula creation and balloon dilation. The applicant believes that CMS should focus on the actions involved in considering differences in the mechanism of action. Per the applicant, the hardware configuration of the device may be the same, but the clinical pattern of use has changed, and the action it accomplishes is different as well.

In response to the note that the application did not address differences in mechanism of action between Ellipsys and WavelinQ™ EndoAVF System, the applicant reiterated differences between the two pAVF systems described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58702), where CMS recognized that WavelinQ uses a unique mechanism of action, and stated that CMS should carry that logic through and similarly determine that Ellipsys uses a new mechanism of action as well.

Response: We appreciate the information provided by the applicant regarding the newness criterion. We agree that Ellipsys and WavelinQ have two unique mechanisms of action. In regard to the mechanism of action of the current version of Ellipsys as compared to the previous version, we continue to have concerns as stated in the proposed rule and as described by a commenter. As stated in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. We note that even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. Although the applicant maintains that the change in the Ellipsys IFU represents a new mechanism of action, we believe that regardless of whether the procedural steps have changed, the manner in which the device functions is unchanged from the De Novo version and therefore does not represent a new mechanism of action. That is, both the current and De Novo versions of the Ellipsys System use thermal resistance energy to create a percutaneous fistula in the same location using the same catheter. As per the commenter and the FDA 510(k) clearance, no changes have been made to the device or the manner in which it creates a percutaneous anastomosis for the clearance of the current version. We agree with the commenter that though the additional

[172] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. 510(k) Summary No. K1191114. 2019. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191114.pdf.*

[173] Hull JE, Jennings W, *et al.,* ''The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access,'' *Journal of Vascular and Interventional Radiology* 2018; 29: 149–158.

step of balloon angioplasty may assist with maturation, it does not change the method by which the fistula is created.

Futhermore, we agree with the applicant and commenter that the two versions of the technology are intended to treat the same or similar disease in the same or similar patient population—patients with ESRD requiring hemodialysis access and eligible for a percutaneous fistula, and cases involving the technologies would be assigned to the same MS–DRGs. Because the current version of Ellipsys meets all three of the substantial similarity criteria, we believe the current version of Ellipsys is substantially similar to the original version. Therefore, we consider the beginning of the newness period for the device to begin on June 22, 2018, which is the date that the original version of the Ellipsys system received FDA approval. Because the 3-year anniversary date of the entry of Ellipsys onto the U.S. market (June 22, 2021) will occur in FY 2021, the device does not meet the newness criterion and it is not eligible for new technology add-on payments for FY 2022. We note that we received public comments with regard to the cost and substantial clinical improvement criteria for this technology, but because we have determined that the technology does not meet the newness criterion and therefore is not eligible for approval for new technology add-on payments for FY 2022, we are not summarizing comments received or making a determination on those criteria in this final rule.

f. ENSPRYNG™ (satralizumab-mwge)

Genentech, Inc. submitted an application for new technology add-on payments for the ENSPRYNG™ (satralizumab-mwge) injection for FY 2022. According to the applicant, ENSPRYNG™ is indicated by the FDA for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. ENSPRYNG™ is the first subcutaneous, first self-administered, and third FDA-approved drug for the treatment of this severe chronic autoimmune disease of the central nervous system.[174] The applicant stated, due to the severity of relapses, relapse prevention is a key disease management priority. Patients who relapse are often admitted to the hospital for acute treatment. According to the applicant, with every relapse, patients are at risk of becoming blind or paralyzed, and thus it is critical to minimize the risk of future relapses by initiating maintenance treatment with a therapy such as ENSPRYNG™ in a timely manner while the patient is still admitted. Therefore, according to the applicant, ENSPRYNG™ should be approved for new technology add-on payments in order to maximize the likelihood that this especially sick patient population can start the treatment they need while in the inpatient setting.

According to the applicant, NMOSD is a rare, inflammatory, potentially life-threatening autoimmune central nervous system (CNS) disorder characterized primarily by severe, unpredictable relapses of optic neuritis and/or acute longitudinally extensive transverse myelitis (LETM).[175] The applicant asserted that NMOSD has an estimated prevalence of 0.1–10 per 100,000 individuals, affecting nearly 15,000 individuals in the United States.[176] NMOSD occurs in children [177] and adults [178] of all races [179] and disproportionately affects African and Asian females aged 30 to 40 years.[180] According to the applicant, the (bilateral) optic neuritis and/or LETM that are characteristic of NMOSD result from inflammation of the optic nerve, spinal cord,[181] and brainstem,[182] but other regions of the CNS may be affected as well. The vast majority of patients (80%–90%) experience repeated relapses, and disability accumulates with each relapse.[183] Around 60% of patients relapse within one year of diagnosis, and 90% relapse within 3 years.[184] Compared with patients who experience an isolated attack, patients with relapsing disease have greater disease-related clinical burden, and upward of 83% of patients do not fully recover after subsequent relapses.[185]

According to the applicant, the negative impact of NMOSD on patient quality of life (QoL) is predominantly a result of physical disability, pain, vision impairment, and bowel and bladder dysfunction.[186] Disease-induced disability and symptoms have a considerable impact on patients' ability to work and thrive in social activities and personal relationships.[187] The applicant added that the loss of motor and sensory function leads to approximately 50% of patients requiring a wheelchair [188] and 62% of patients becoming functionally blind [189] within 5 years of diagnosis.[190] Therefore, according to the applicant, it is critical that treatments that consistently and effectively reduce the risk of relapse are initiated rapidly in patients diagnosed with NMOSD.

With respect to the newness criterion, ENSPRYNG™ received FDA BLA approval on August 14, 2020. The applicant added that ENSPRYNG™ was

[174] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020. SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019. UPLIZNA (inebilizumab) [prescribing information]. Gaithersburg, MD: Viela Bio, Inc.; 2020.

[175] Jarius S, Ruprecht K, Wildemann B, et al. Contrasting disease patterns in seropositive and seronegative neuromyelitis optica: A multicentre study of 175 patients. J. Neuroinflammation 2012;9(1) doi:10.1186/1742–2094–9–14.

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[181] Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorder (NMOSD). *https://wearesrna.org/living-with-myelitis/disease-information/neuromyelitis-optica-spectrum-disorder/diagnosis/#nmosd.* Accessed August 19, 2020.

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granted Fast Track designation [191] and Breakthrough Therapy designation [192] by the FDA. The applicant stated that ENSPRYNG™ was not commercially available until August 24, 2020 because the applicant had to wait for final approval for printing and labeling as well as customs and importation. The recommended loading dosage of ENSPRYNG™ for the first three administrations is 120 mg by subcutaneous injection at Weeks 0, 2, and 4, followed by a maintenance dosage of 120 mg every four weeks. The applicant submitted a request for an ICD–10–PCS code to uniquely identify the administration of ENSPRYNG™ beginning FY 2022 and was granted approval for the following code effective October 1, 2021: XW01397 (Introduction of satralizumab-mwge into subcutaneous tissue, percutaneous approach, new technology Group 7).

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. The applicant stated that there are limited treatment guidelines available for NMOSD with the most recent US guidelines published in 2012. These US NMOSD treatment guidelines exclusively recommend off-label drugs: Azathioprine, with or without prednisone; mycophenolate mofetil, with or without prednisone; rituximab; or prednisone alone.[193] The applicant stated that there are presently two other FDA-approved therapies for patients with AQP4-IgG positive NMOSD: SOLIRIS® (eculizumab),[194] which was approved in 2019, and UPLIZNA® (inebilizumab-cdon), which was approved in 2020.[195]

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the application stated that ENSPRYNG™ is an interleukin-6 (IL–6) receptor antagonist indicated for the treatment of NMOSD in adult patients who are AQP4-IgG positive.[196] According to the applicant, ENSPRYNG™ targets soluble and membrane-bound IL–6 receptors to inhibit IL–6 signaling and subsequently disrupt downstream inflammatory effects that contribute to the pathophysiology of NMOSD; [197] ENSPRYNG™ dissociates from the IL–6 receptor at an acidic pH within endosomes and is recycled to circulation, prolonging the plasma half-life of the drug.[198]

The applicant next identified other drugs used to treat NMOSD and their corresponding mechanisms of action. According to the applicant, these current treatments include: SOLIRIS®, for which a precise mechanism of action is unknown but is presumed to involve inhibition of AQP4-IgG-induced terminal complement C5b-9 deposition; [199] UPLIZNA®, for which a precise mechanism of action is unknown but is presumed to involve binding to CD19, a surface antigen present on pre-B and mature B cells; [200] azathioprine, for which a precise mechanism of action is unknown; [201] Rituxan, which targets CD20 antigen on B cells and leads to profound B cell depletion, principally over an antibody-dependent cell cytotoxicity mechanism; [202] mycophenolate mofetil, which is an immunosuppressive and an inhibitor of inosine monophosphate dehydrogenase and therefore of the guanosine nucleotide synthesis pathway upon which T and B cells depend; [203] and prednisone, which is a synthetic adrenocortical steroid drug with predominately corticosteroid properties.[204] The applicant concluded that none of these current drugs are characterized by their binding and blocking of soluble and membrane-bound IL–6 receptors to inhibit IL–6 signaling. Therefore, the applicant believes ENSPRYNG™ has a unique and distinct mechanism of action.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant acknowledged that ENSPRYNG™ may be assigned to the same MS–DRG when compared to existing technology. Per the applicant, cases representing patients who may be eligible for treatment with ENSPRYNG™ map to MS–DRGs 058, 059, and 060.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that the use of ENSPRYNG™ may not involve the treatment of the same or similar patient population when compared with an existing technology because: (1) Current technologies such as SOLIRIS® may be contraindicated in patients with unresolved serious Neisseria meningitidis infections; and (2) SOLIRIS® and UPLIZNA® are administered as IV infusions which not all patients may be willing to receive.

In summary, the applicant asserted ENSPRYNG™ meets the newness criterion because it is the only treatment for NMOSD that works specifically by suppressing IL–6 signaling, and because it may not involve the treatment of the same or similar patient population as existing technology.

In the proposed rule (86 FR 25253), we noted that the applicant stated that the use of ENSPRYNG™ may not involve treatment of the same or similar patient population when compared to SOLIRIS® with regard to the treatment of patients with unresolved serious Neisseria meningitidis infection and with regard to the treatment of patients unwilling to receive an IV infusion. However, we questioned if UPLIZNA® may also be a treatment option for patients with meningococcal disease. We further questioned whether patients who are unwilling to receive an IV infusion would constitute a new patient

[191] US Department of Health and Human Services. FDA Approves Treatment for Rare Disease Affecting Optic Nerves, Spinal Cord. *https://www.fda.gov/news-events/press-announcements/fda-approves-treatment-rare-disease-affecting-optic-nerves-spinal-cord.* Accessed September 10, 2020.

[192] Genentech, USA Inc. FDA Approves Genentech's Enspryng for Neuromyelitis Optica Spectrum Disorder. *https://www.gene.com/media/press-releases/14873/2020-08-14/fda-approves-genentechs-enspryng-for-neu.* Accessed September 10, 2020.

[193] Kimbrough DJ, Fujihara K, Jacob A, et al. Treatment of Neuromyelitis Optica: Review And Recommendations. Mult Scler Relat Disord. 2012;1(4):180–187. doi:10.1016/j.msard.2012.06.002.

[194] SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.

[195] UPLIZNA (inebilizumab) [prescribing information]. Gaithersburg, MD: Viela Bio, Inc.; 2020.

[196] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[197] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

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[199] SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.

[200] UPLIZNA (inebilizumab) [prescribing information]. Gaithersburg, MD: Viela Bio, Inc.; 2020.

[201] IMURAN (azathioprine) [prescribing information]. Roswell, GA: Sebela Pharmaceuticals Inc.; 2018.

[202] RITUXAN (rituximab) [prescribing information]. South San Francisco, CA: Genentech, Inc.; 2019.

[203] Allison AC, Eugui EM. Mycophenolate Mofetil And Its Mechanisms of Action. Immunopharmacology 2000;47(2–3)85–118. doi:10.1016/s0162–3109(00)00188–0.

[204] RAYOS (prednisone) [prescribing information]. Lake Forest, IL: Horizon Therapeutics USA, Inc.; 2019.

population for NMOSD. We invited public comment on whether ENSPRYNG™ involves the treatment of the same or similar patient population when compared to existing technologies.

We invited public comments on whether ENSPRYNG™ is substantially similar to other technologies and whether ENSPRYNG™ meets the newness criterion.

Comment: We received a public comment regarding the newness criterion. The commenter stated that ENSPRYNG™ is not substantially similar to UPLIZNA®. The commenter explained that UPLIZNA® and ENSPRYNG™ have different mechanisms of action. The commenter stated that while ENSPRYNG™'s mechanism of action involves the binding and blocking of soluble and membrane-bound IL–6 receptors to inhibit IL–6 signaling, UPLIZNA®'s mechanism of action involves binding to CD19, a cell surface antigen present on pre-B and mature B lymphocytes, and results in antibody-dependent, cell-mediated B cell depletion. The commenter also explained that UPLIZNA® and ENSPRYNG™ are not substantially similar because UPLIZNA® is the only NMOSD treatment that is administered twice per year, after two initial start-up doses. The commenter stated that the maintenance dose schedule of twice per year, following the initial start-up doses, presents an important benefit for NMOSD patients wishing to receive treatment once every six months and for patients who do not wish to or are unable to self-administer injections. Finally, the commenter responded to CMS' request for information on whether UPLIZNA® is a treatment option for NMOSD patients with meningococcal disease. The commenter stated that UPLIZNA® is not contraindicated in patients with unresolved serious *Neisseria meningitidis* infections and clarified that this was not a serious adverse event reported during the Phase 3 clinical trials. The commenter concluded that based on the different mechanisms of action, routes of administration, and recommended dosing schedules for maintenance treatment, UPLIZNA® and ENSPRYNG™ are not substantially similar.

The applicant also submitted a comment addressing concerns raised by CMS in the proposed rule regarding whether ENSPRYNG™ meets the newness criterion. In response to our concerns that UPLIZNA® may also be a treatment option for patients with meningococcal disease, the applicant stated that UPLIZNA® may or may not be an option for NMOSD patients with meningococcal disease. However, the applicant pointed out that although UPLIZNA® is not specifically contraindicated in patients with meningococcal disease, its prescribing information warns prescribers about PML, which has been observed in patients treated with other B-cell-depleting antibodies and other therapies that affect immune competence, like UPLIZNA®. In response to our concerns regarding whether patients who are unwilling to receive an IV infusion constitute a new patient population for NMOSD, the applicant stated that ENSPRYNG™ is the only FDA-approved option for NMOSD patients that are unwilling or unable to receive infusions, perhaps due to difficulties associated with their venous access.

Response: We appreciate the commenters' input. Based on the comments received and the information submitted as part of the FY 2022 new technology add-on payment application for ENSPRYNG™, as discussed in the proposed rule (86 FR 25070 through 25790) and in this final rule, we concur with the comments received that ENSPRYNG™ has a unique mechanism of action when compared to existing technologies because the other technologies are not characterized by their binding and blocking of soluble and membrane-bound IL–6 receptors to inhibit IL–6 signaling, as ENSPRYNG™'s mechanism of action does and, therefore, we believe that ENSPRYNG™ is not substantially similar to existing treatment options. However, we note that we disagree with the applicant that ENSPRYNG™ does not involve the treatment of the same or similar patient population as existing technologies for two reasons. As the first commenter stated, UPLIZNA®, another treatment for NMOSD, is not contraindicated in patients with unresolved serious *Neisseria meningitidis* infections, and therefore, may also be a treatment option for patients with meningococcal disease. In addition, the applicant noted that existing technologies are administered via IV infusion, which not all patients may be willing or able to receive. We do not agree that patients who are unwilling to receive an IV infusion constitute a new patient population for NMOSD. Additionally, although IV infusion may be difficult to administer for some patients, we are not aware of cases where it is impossible.

Therefore, we believe ENSPRYNG™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence when ENSPRYNG™ became commercially available, on August 24, 2020.

With regard to the cost criterion, the applicant provided two cost analyses, with the first being an update of the analysis used in FY 2021 by the applicant for SOLIRIS®, which is also indicated for NMOSD, and the second which is specific to ENSPRYNG®.

Under the first analysis, the applicant searched the FY 2019 MedPAR database for cases reporting ICD–10–CM code G36.0 in the primary and/or admitting position, which resulted in 583 cases. The applicant imputed one case where an MS–DRG had a case volume lower than 11, resulting in 556 cases mapping to 30 MS–DRGs. The applicant stated that it restricted the analysis to MS–DRGs 058, 059, and 060, which accounted for 92.1% of all cases identified. The applicant also excluded cases that were not included in the FY 2021 Proposed Rule Impact File from this analysis, resulting in a final case count of 466 cases mapping to three MS–DRGs. Using a CCR of 0.343 (national other services average CCR), the applicant then removed all charges in the drug cost center, all charges in the blood cost center, and an additional $12,000 of cost for plasma exchange procedural costs for cases with non-zero charges in the blood cost center, for charges for related and prior technologies. The applicant applied an inflation factor of 13.1%, which per the applicant is the outlier charge inflation factor used in the FY 2021 IPPS/LTCH PPS final rule, to update the standardized charges from FY 2019 to FY 2021. We note that the applicant appears to have used the FY 2021 IPPS/LTCH PPS proposed rule inflation factor rather than the 2-year inflation factor from the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent (85 FR 59038), which would have increased the inflated charges. Finally, the applicant added charges for the technology by multiplying the cost of ENSPRYNG™, based on an average of 1.22 doses per patient, by the inverse of the national average drug CCR of 0.187 from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). The applicant calculated a final inflated average case-weighted standardized charge per case of $150,154, which exceeds the case-weighted threshold of $47,813.

For the second analysis, the applicant used the same sample of cases (466) from the first analysis, as identified in the FY 2019 MedPAR database with the ICD–10–CM code G36.0 and with the same sample restrictions. In this analysis, the applicant did not remove

charges for related or prior technologies because, per the applicant, ENSPRYNG™ is anticipated to neither replace plasma exchange nor be used as a monotherapy in all patients. The applicant standardized and inflated the charges, as well as added charges for ENSPRYNG™ using the same methodology as the first analysis, described previously. The applicant calculated a final inflated average case-weighted standardized charge per case of $175,021, which exceeded the case-weighted threshold of $47,813. The applicant asserted that ENSPRYNG™ meets the cost criterion based on these analyses.

Based on the information provided by the applicant, we stated that it was uncertain to us why the national other services average CCR was used to inflate costs to charges in the first analysis when the applicant indicated that it removed charges from the drugs cost center and blood cost center. We sought public comment on whether this or another CCR, such as a CCR for drugs or blood and blood products, would be more appropriate. Furthermore, in the event that a MS–DRG has fewer than 11 cases, we stated that the applicant should impute a minimum case number of 11.

We invited public comments on whether ENSPRYNG™ meets the cost criterion, including whether the use of another CCR would substantially alter the results of the applicant's analysis.

Comment: The applicant submitted a comment addressing the concerns raised by CMS in the proposed rule regarding whether ENSPRYNG™ meets the cost criterion. The applicant reiterated that CMS was provided with two cost analyses in its original application: An updated version of the analysis used in FY 2021 by the new technology add-on payment applicant for SOLIRIS® and a second analysis that was the applicant's original work and aligned more closely with how ENSPRYNG™ would be used. The applicant first noted the following updates to both analyses per CMS' feedback: (1) Imputing a minimum case number of 11 and (2) using the 2-year inflation factor from the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent. The applicant then addressed CMS' concern regarding the appropriateness of the CCR used to inflate cost to charges in these analyses. With respect to the first analysis, the applicant indicated that CMS accepted the use of the ''other services'' national average cost-to-charge ratio for SOLIRIS® and that its use in the first scenario is therefore appropriate. The applicant noted that while a different CCR (such as the CCR for drugs or blood and blood products, as suggested by CMS) might be more appropriate, it provided CMS with the first analysis for contextual purposes only and did not want to comment on the validity of the cost analysis for SOLIRIS®. With respect to the second analysis, the applicant maintained that since ENSPRYNG™ is not anticipated to replace plasma exchange or be used as a monotherapy in all patients, there are no charges to remove. Per the applicant, the issue of which CCR is more appropriate to use when removing charges is therefore moot, and did not apply to the second analysis.

After following the methodology described previously with the exception of the imputed case value of 11 and updated inflation factor, the applicant presented the results of the revised cost analyses by MS–DRG.

Scenario #1:

MS-DRG	Description	Case %	Table 10 Threshold	Standardized Charges	Difference
059	Multiple Sclerosis and Cerebellar Ataxia with CC	45.7%	$47,326	$151,169	$103,843
060	Multiple Sclerosis and Cerebellar Ataxia without CC/MCC	35.6%	$42,724	$140,190	$97,466
058	Multiple Sclerosis and Cerebellar Ataxia with MCC	18.7%	$58,716	$166,934	$108,218

Scneario #2:

MS-DRG	Description	Case %	Table 10 Threshold	Standardized Charges	Difference
059	Multiple Sclerosis and Cerebellar Ataxia with CC	45.7%	$47,326	$176,070	$128,744
060	Multiple Sclerosis and Cerebellar Ataxia without CC/MCC	35.6%	$42,724	$161,915	$119,191
058	Multiple Sclerosis and Cerebellar Ataxia with MCC	18.7%	$58,716	$197,840	$139,124

The applicant stated that, under both revised analyses, the average case-weighted standardized charge per case exceeded the revised case-weighted threshold and therefore ENSPRYNG™ meets the cost criterion.

Response: We thank the applicant for submitting its comments addressing the concerns we raised in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070 through 25104), including with respect to the use of the ''other services'' CCR, and its submission of a revised cost analysis. Based on the information provided by the applicant, because the final inflated average case-weighted standardized charge per case exceeded the case-weighted threshold of amount in both scenarios, we agree with the applicant that ENSPRYNG™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that ENSPRYNG™ represents a substantial clinical improvement in the following ways: (1) It significantly improves clinical outcomes relative to services or technologies previously available for the treatment of NMOSD in adult patients who are AQP4-IgG positive; (2) these improvements are not accompanied by serious safety concerns; (3) ENSPRYNG™ is the only FDA-approved treatment for NMOSD that is subcutaneously administered; [205] and (4) the totality of circumstances demonstrates ENSPRYNG™, relative to technologies previously available, substantially improves the treatment of Medicare beneficiaries. The applicant submitted two recent studies to support their claims of substantial clinical improvement over existing technologies.

The SAkuraStar (NCT02073279) [206] study was a Phase 3, double-blind, placebo-controlled, parallel-group trial at 44 investigational sites in 13 countries to assess the safety and efficacy of ENSPRYNG™ monotherapy in patients with NMOSD. 95 (57%) of 168 screened participants aged 18–74 years with AQP4-IgG positive or negative NMOSD met the inclusion criteria and were randomly assigned (2:1) to treatment with ENSPRYNG™ 120mg (n = 63) or visually matched placebo (n = 32). Inclusion criteria included participants who had experienced at least one documented NMOSD attack or relapse in the previous 12 months and had a score of 6.5 or less on the Expanded Disability Status Scale, while exclusion criteria included clinical relapse 30 days or fewer before baseline. The primary endpoint was time to the first protocol-defined relapse, based on the intention-to-treat (ITT) population (AQP4-IgG positive and negative) (n=95), and analyzed with stratification for two randomization factors (previous therapy for prevention of attacks and nature of the most recent attack). Treatment in both arms was given subcutaneously at weeks 0, 2, 4, and every 4 weeks thereafter. The double-blind phase was due to last until 44 protocol-defined relapses occurred or 1.5 years after random assignment of the last patient enrolled, whichever occurred first. Participants could enter an open-label phase after the occurrence of a protocol-defined relapse or at the end of the double-blind phase. Protocol-defined relapses occurred in 19 (30%) patients receiving satralizumab and 16 (50%) receiving placebo (hazard ratio 0.45, 95% CI 0.23–0.89; p = 0.018). 473.9 adverse events per 100 patient-years occurred in the satralizumab group and 495.2 per 100 patient-years in the placebo group. The authors noted that the incidence of serious adverse events and adverse events leading to withdrawal was similar between groups.

According to the applicant, this study demonstrated that the time to the first relapse was significantly longer in ENSPRYNG™ treated patients compared with patients who received a placebo (risk reduction, 55%; hazard ratio, 0.45 (95% CI 0.23, 0.89); p = 0.0184). In the AQP4-IgG positive population, there was a 74% risk reduction and a hazard ratio of 0.26 (95% CI 0.11, 0.63; p = 0.0014). The results in the subgroup of AQP4-IgG negative patients were not statistically significant.[207] [208] The annualized relapse

[205] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[206] Traboulsee A, Greenberg BM, Bennett JL, et al. Safety And Efficacy of Satralizumab Monotherapy In Neuromyelitis Optica Spectrum Disorder: A Randomised, Double-Blind, Multicentre, Placebo-Controlled Phase 3 Trial. Lancet Neurol. 2020;19(5):402–412. doi:10.1016/S1474–4422(20)30078–8.

[207] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

Traboulsee A, et al. Efficacy of satralizumab monotherapy in prespecified subgroups of SAkuraStar, a phase 3 study in patients with neuromyelitis optica spectrum disorder. Oral Presentation at: Annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum; West Palm Beach, FL, USA; February 27–29, 2020.

[208] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

Traboulsee A, et al. Efficacy of satralizumab monotherapy in prespecified subgroups of SAkuraStar, a phase 3 study in patients with neuromyelitis optica spectrum disorder. Oral

Continued

rate for AQP4-IgG positive patients was 0.1 (95% CI, 0.05–0.2) in the ENSPRYNG™ group and 0.5 (95% CI, 0.3–0.9) in the placebo group.[209] The proportion of relapse-free AQP4-IgG positive patients at week 96 was 77% in the ENSPRYNG™ group and 41% in the placebo group.[210] According to the applicant, the study concluded that ENSPRYNG™ monotherapy reduced the rate of NMOSD relapse compared with placebo in the overall trial population and had a favorable safety profile.

In the second Phase 3, randomized, double-blind, placebo-controlled study submitted by the applicant, the SAkuraSky (NCT02028884) [211] trial, 83 patients with NMOSD who were seropositive or seronegative for AQP4-IgG were randomly assigned (1:1) to receive either 120 mg of satralizumab (n=41) or placebo (n=42) administered subcutaneously at weeks 0, 2, and 4 and every 4 weeks thereafter, in addition to stable IST. The primary end point was the first protocol-defined relapse in a time-to-event analysis. Key secondary end points were the change from baseline to week 24 in the visual-analogue scale (VAS) pain score (range, 0 to 100, with higher scores indicating more pain) and the Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT–F) score (range, 0 to 52, with lower scores indicating more fatigue). Safety was also assessed.

The results of the SAkuraSky trial demonstrated that the median treatment duration with satralizumab in the double-blind period was 107.4 weeks. Relapse occurred in 8 patients (20%) receiving satralizumab and in 18 (43%) receiving placebo (hazard ratio, 0.38; 95% confidence interval [CI], 0.16 to 0.88). Multiple imputations for censored data (including patients who discontinued the trial, received rescue therapy, had a change in baseline treatment, or were continuing in the trial at the data-cutoff date) resulted in hazard ratios ranging from 0.34 to 0.44 (with corresponding P values of 0.01 to 0.04). Among the 55 AQP4-IgG–seropositive patients, relapse occurred in 11% of those in the satralizumab group and in 43% of those in the placebo group (hazard ratio, 0.21; 95% CI, 0.06 to 0.75); among 28 AQP4-IgG–seronegative patients, relapse occurred in 36% and 43%, respectively (hazard ratio, 0.66; 95% CI, 0.20 to 2.24). The between-group difference in the change in the mean VAS pain score was 4.08 (95% CI, −8.44 to 16.61); the between-group difference in the change in the mean FACIT–F score was −3.10 (95% CI, −8.38 to 2.18). The rates of serious adverse events and infections did not differ between groups.

In support of the applicant's claim that ENSPRYNG™ significantly improves clinical outcomes relative to services or technologies previously available for the treatment of NMOSD in adult patients who are AQP4-IgG positive, the applicant stated that patients treated with ENSPRYNG™ plus IST exhibited a significantly longer time to first relapse when compared to placebo. This also included a risk reduction of 62% in patients treated with ENSPRYNG™ plus IST when compared with patients who received a placebo plus IST and a 79% risk reduction in the AQP4-IgG positive population. Results in the AQP4-IgG negative patient subgroup were not statistically significant.[212] The proportion of relapse free AQP4-IgG positive patients at week 96 was 92% in ENSPRYNG™ plus IST group and 53% in the placebo plus IST group.[213]

According to the applicant's second claim, substantial improvements in clinical efficacy are not accompanied by serious concerns. In the SAkuraSky trial, 90% of patients in the ENSPRYNG™ plus IST group had at least one adverse event compared to 95% in the placebo plus IST group.[214] The safety profile of ENSPRYNG™ in the OST period was consistent with the double-blind period. There were no deaths or anaphylactic reactions, rates of AEs and serious AEs did not increase with longer exposure to ENSPRYNG™; and the most frequently reported AEs in the OST period were consistent with the double-blind period.[215]

The applicant's third claim concerns the flexibility provided to patients by the option to self-administer ENSPRYNG™. According to the applicant, ENSPRYNG™ is the only FDA-approved treatment for NMOSD that is administered subcutaneously.[216] Once treatment is initiated during inpatient hospital admission, upon discharge and having received adequate training on how to perform the injection, an adult patient/caregiver may administer all subsequent doses of ENSPRYNG™ at home if the treating physician determines that it is appropriate and the adult patient/caregiver can perform the injection technique. According to the applicant, self-administration provides the patient the option to continue the therapy initiated in the hospital while in the convenience of their own home, with reduced disruption to daily life. The applicant stated that additionally, the option to self-administer provides flexibility to patients, as they can bring their medication with them while traveling without having to worry if there is an infusion site nearby. The applicant claims this may potentially reduce the rate of hospital readmissions.

In their fourth claim, the applicant stated the totality of circumstances otherwise demonstrate that ENSPRYNG™, relative to technologies previously available, substantially improves the treatment of Medicare beneficiaries. The applicant asserted that a cross trial comparison between ENSPRYNG™ and SOLIRIS® (approved for new technology add-on payment in FY 2021) cannot be made due to differences in trial design and study population. However, the applicant noted the following distinctions between ENSPRYNG™ and SOLIRIS® and their clinical trials. Per the applicant, the first distinction is that in the registrational study for SOLIRIS®, a higher proportion of patients receiving SOLIRIS® than those receiving a placebo discontinued their participation in the clinical trial (17% vs 6%).[217]

Presentation at: Annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum; West Palm Beach, FL, USA; February 27–29, 2020.

[209] Traboulsee A, et al. Efficacy of satralizumab monotherapy in prespecified subgroups of SAkuraStar, a phase 3 study in patients with neuromyelitis optica spectrum disorder. Oral Presentation at: Annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum; West Palm Beach, FL, USA; February 27–29, 2020.

[210] Traboulsee A, Greenberg BM, Bennett JL, et al. Safety And Efficacy of Satralizumab Monotherapy In Neuromyelitis Optica Spectrum Disorder: A Randomised, Double-Blind, Multicentre, Placebo-Controlled Phase 3 Trial. Lancet Neurol. 2020;19(5):402–412. doi:10.1016/S1474–4422(20)30078–8.

[211] U.S. Department of Health and Human Services. Active Study | Neuromyelitis Optica Spectrum Disorder. *https://clinicaltrials.gov/ct2/results?cond=&term=NCT020288884&cntry=&state=&city=&dist=*. Accessed August 14, 2020.

[212] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[213] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[214] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[215] Greenberg B, Seze JD, Fox E. et al. Safety of satralizumab in neuromyelitis optica spectrum disorder (NMOSD): Results from the open-label extension periods of SAkuraSky and SAkuraStar Presentation at: Americas Committee for treatment and research in Multiple Sclerosis (ACTRIMS); September 2020; Virtual

[216] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[217] Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in Aquaporin-4–Positive Neuromyelitis

During the double-blind period of SAkuraSky trial, however, a total of three patients (7%) in the ENSPRYNG™ group and 10 patients (24%) in the placebo group discontinued the trial agent.[218] The applicant stated that discontinuation of SOLIRIS® may be associated with relapse and hospitalization. The second distinction made by the applicant is that the prescribing information for ENSPRYNG™ [219] does not bear a black-box warning, in contrast to that of SOLIRIS®.[220] The third distinction is that patients must be vaccinated against *Neisseria meningitidis* before receiving SOLIRIS® [221] and no such requirement applies to ENSPRYNG™.[222] The fourth and final distinction made by the applicant highlights duration of treatment. In the SAkuraSky trial, the mean period of treatment in the double-blind period was 94.1 ± 72.6 weeks in the ENSPRYNG™ group and 66.0 ± 61.4 weeks in the placebo group.[223] However, the median trial durations were shorter in the SOLIRIS® trial, at 90.93 and 43.14 weeks (minimum-maximum, 6.4–211.1 and 8.0–208.6) for the SOLIRIS® and placebo groups, respectively.[224]

In connection with the applicant's fourth claim to support substantial clinical improvement, the applicant stated that both the SAkuraStar [225] and SAkuraSky [226] clinical trials included comparator arms. In SAkuraStar, an exclusion criterion was IST use, whereas in SAkuraSky, patients were permitted to continue baseline treatment with a stable dose of the IST agents in addition to the trial drug. This allowed the efficacy of ENSPRYNG™ to be assessed both in patients who were receiving one of the IST agents for their NMOSD and in the others who were receiving nothing at all. The applicant stated that in contrast, SOLIRIS® was tested only in a single Phase 3 clinical trial where the primary end point was the first adjudicated relapse in the population of patients taking stable-dose IST and either SOLIRIS® or placebo; the efficacy of SOLIRIS® monotherapy was a sub analysis,[227] and UPLIZNA® was tested only in a single Phase 3 clinical trial as a monotherapy with only a 28-week randomized, controlled period.[228] According to the applicant, ENSPRYNG™ has received approval by regulatory authorities in Japan,[229] Canada, and Switzerland [230] for the treatment of both adults and adolescents (12–17 years of age) with NMOSD. The applicant asserted that patients in the ENSPRYNG™ clinical trials likely are representative of Medicare patients despite their mean ages (45.3 years for the ENSPRYNG™ arm of SAkuraStar [231] and 40.8 years for the ENSPRYNG™ arm of SAkuraSky [232]) being less than 65, as NMOSD is so severe that patients may qualify for disability accompanied by Medicare benefits regardless of their age.[233] The applicant explained that a severe onset attack causing increased disability is reported to occur in 45% of patients with NMOSD [234] and that 52.4% of US-based NMOSD patients report severe problems with mobility,[235] which is consistent with definitions of disability used by the Social Security Administration (SSA).[236] Per the applicant, SSA maintains a list of impairments considered severe enough to prevent gainful activity. Though NMOSD is not listed, multiple sclerosis (MS) is,[237] and the two conditions are frequently confused due to similarities between clinical presentations.[238] According to the applicant, the SSA is open to allowing people to qualify for disability by showing their condition is as severe as one that is on the list.[239]

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for ENSPRYNG™, we noted that while the applicant provided data comparing ENSPRYNG™ to placebo with or without IST, the applicant did not provide data to demonstrate improved outcomes over existing FDA approved treatments for NMOSD. While the applicant stated reasons why a comparison could not be made, we stated that additional information would help inform our assessment of whether ENSPRYNG™ demonstrates a significant clinical improvement over existing technologies for outcomes such as time to first relapse and annual relapse rate. In addition, we stated that while we understand that there may be potential benefits related to the self-administrative delivery of ENSPRYNG™, we questioned if the benefits are related only to the outpatient administration of the medication and whether they would demonstrate improved clinical outcomes that represent a substantial clinical improvement in the inpatient setting. We invited public comments on

Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(7)614–625. doi:10.1056/nejmoa1900866.

[218] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[219] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[220] SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.

[221] SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.

[222] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[223] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[224] Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in Aquaporin-4–Positive Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(7)614–625. doi:10.1056/nejmoa1900866.

[225] Traboulsee A, Greenberg BM, Bennett JL, et al. Safety And Efficacy of Satralizumab Monotherapy In Neuromyelitis Optica Spectrum Disorder: A Randomised, Double-Blind, Multicentre, Placebo-Controlled Phase 3 Trial. Lancet Neurol. 2020;19(5):402–412. doi:10.1016/S1474–4422(20)30078–8.

[226] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019; 381(22)2114–2124. doi:10.1056/nejmoa1901747.

[227] Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in Aquaporin-4–Positive Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(7)614–625. doi:10.1056/nejmoa1900866.

[228] Cree BAC, Bennett JL, Kim HJ, et al. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N–MOmentum): a double-blind, randomised placebo-controlled phase ⅔ trial. Lancet 2019;394(10206)1352–1363. doi:10.1016/s0140–6736(19)31817–3.

[229] F. Hoffmann-La Roche Ltd. Roche's ENSPRYNG (satralizumab) Approved In Japan For Adults And Children With Neuromyelitis Optica Spectrum Disorder. *https://www.roche.com/media/releases/med-cor-2020-06-29.htm.* Accessed August 14, 2020.

[230] Heo Y. Satralizumab: First Approval. Drugs 2020;80(14)1477–1482. doi:10.1007/s40265–020–01380–2.

[231] Traboulsee A, Greenberg BM, Bennett JL, et al. Safety And Efficacy of Satralizumab Monotherapy In Neuromyelitis Optica Spectrum Disorder: A Randomised, Double-Blind, Multicentre, Placebo-Controlled Phase 3 Trial. Lancet Neurol. 2020;19(5):402–412. doi:10.1016/S1474–4422(20)30078–8.

[232] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[233] Social Security Administration. Medicare Information. *https://www.ssa.gov/disabilityresearch/wi/medicare.htm.* Accessed September 10, 2020.

[234] Kim S, Mealy MA, Levy M, et al. Racial differences in neuromyelitis optica spectrum disorder. Neurology 2018;91(22)e2089-e2099. doi:10.1212/wnl.0000000000006574.

[235] Mealy MA, Boscoe A, Caro J, et al. Assessment of Patients with Neuromyelitis Optica Spectrum Disorder Using the EQ–5D. Int. J. MS Care 2018; 21(3)129–134. doi:10.7224/1537–2073.2017–076.

[236] Social Security Administration. How You Qualify. *https://www.ssa.gov/benefits/disability/qualify.html.* Accessed October 2, 2020.

[237] Social Security Administration. Disability Evaluation Under Social Security. *https://www.ssa.gov/disability/professionals/bluebook/11.00-Neurological-Adult.htm#11_09.* Accessed September 10, 2020.

[238] Etemadifar M, Nasr Z, Khalili B, Taherioun M, Vosoughi R. Epidemiology of Neuromyelitis Optica In The World: A Systematic Review And Meta-Analysis. Mult Scler Int. 2015;2015:174720. doi:10.1155/2015/174720.

[239] Social Security Administration. How You Qualify. *https://www.ssa.gov/benefits/disability/qualify.html.* Accessed October 2, 2020.

whether ENSPRYNG™ meets the substantial clinical improvement criterion.

Comment: We received several comments in support of the new technology add-on payment application for ENSPRYNG™ urging the approval of this application to ensure that Medicare beneficiaries with NMOSD will have timely access to appropriate treatment in the inpatient setting for this devastating, rare, autoimmune disease. The commenters highlighted the risk of relapse associated with NMOSD, and the current practice of using ongoing treatment with medications that suppress the immune system to prevent relapse from happening. The commenters explained that approval of the new technology add-on payment for ENSPRYNG™ would minimize the risk of future relapses and potential hospital readmissions by allowing patients to start on a safe and effective maintenance treatment while admitted in the inpatient setting. The commenters referenced the SAkuraStar and SAkuraSky studies, summarized here and in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25254 through 25256), as evidence that ENSPRYNG™ is a safe and effective treatment for NMOSD.

Response: We thank the commenters for sharing their perspective on the new technology add-on payment application for ENSPRYNG™ and have taken these comments into consideration in our determination of substantial clinical improvement, which is discussed later in this section.

Comment: The applicant submitted a comment in response to the concerns raised by CMS in the proposed rule regarding whether ENSPRYNG™ meets the substantial clinical improvement criterion (86 FR 25256). With regard to our concern that the applicant did not submit data to demonstrate improved outcomes over existing FDA approved treatments for NMOSD, the applicant commented that off-label (including IST) therapies are the most appropriate comparator for CMS to use when evaluating whether or not ENSPRYNG™ is a substantial clinical improvement because neither SOLIRIS® nor UPLIZNA® are generally available to inpatient Medicare beneficiaries. The applicant explained that because SOLIRIS® and UPLIZNA® did not have claims in the Statistical Analytical File for CY 2020, the drugs were unavailable in the inpatient setting, and therefore ENSPRYNG™ should not be compared against them for evidence of substantial clinical improvement.

The applicant also commented that ENSPRYNG™ represents a substantial clinical improvement over existing technologies because it is the only FDA-approved treatment for at least two subsets of NMOSD patients who are ineligible for SOLIRIS® and UPLIZNA®: Patients who are not currently vaccinated against *Neisseria meningitidis* and patients at a higher risk of PML. The applicant stated that ENSPRYNG™ is the only FDA-approved treatment for NMOSD that specifically addresses important components of NMOSD pathophysiology without eliminating targeted components of the immune system. The applicant explained that SOLIRIS® is contraindicated in patients who are not currently vaccinated against *Neisseria meningitidis.* Although the vaccination reduces the risk of meningococcal infection, the applicant explained that the SOLIRIS® label states that ''life-threatening and fatal meningococcal infections have occurred in patients treated with SOLIRIS®.'' The applicant also argued that UPLIZNA®'s mechanism of action in targeting B cells may impact cellular reconstitution and long-term humoral memory, which cause potential safety risks including hypogammaglobulinemia and enhanced risk of infections like PML, a viral infection of the brain caused by the JC virus.[240] The applicant cited two technologies that CMS approved for new technology add-on payment technologies, GORE® TAG® (70 FR 47356 through 47359) and CardioWest ™ Temporary Total Artificial Heart System (73 FR 48555 through 48557), as further support that offering treatment options for patients otherwise ineligible for currently available treatments constitutes substantial clinical improvement.

The applicant also commented in response to our concerns in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25256) regarding whether the benefits of ENSPRYNG™ are related only to the outpatient administration of the medication and our concern on whether those benefits would demonstrate improved clinical outcomes that represent a substantial clinical improvement in the inpatient setting. The applicant commented that the benefits associated with the self-administration of ENSPRYNG™ are realized in both the inpatient and outpatient settings, and therefore demonstrate improved clinical outcomes in the inpatient setting. First, the applicant stated that the benefits associated with the self-administration of ENSPRYNG™ in the outpatient setting directly confer benefits in the inpatient setting. As an example, the applicant stated that self-administration of ENSPRYNG™ in the outpatient setting allows patients flexibility to bring their medication with them when they travel without ensuring an infusion site is near their destination. The applicant also explained that due to the severity of NMOSD and its propensity to cause patients experiencing a relapse to be hospitalized, and the clinically-proven ability of ENSPRYNG™ to reduce the incidence of relapse compared to off-label IST treatments, its outpatient use may reduce hospitalizations. Second, the applicant stated that ENSPRYNG™ is the only FDA-approved option in the inpatient setting for patients that are unwilling or unable (perhaps due to difficulties associated with their venous access) to receive IV infusions. Third, the applicant pointed out that CMS has approved several technologies for the new technology add-on payment that are used in both the inpatient and outpatient settings, including DIFICID™ (77 FR 53358), STELARA® (82 FR 38129), CABLIVI® (84 FR 42208), BALVERSA™ (84 FR 42242), ERLEADA™ (84 FR 42247), XOSPATA® (84 FR 42260), XENLETA (85 FR 58732), TECENTRIQ® (85 FR 58684), and IMFINZI® (85 FR 58684).

The applicant commented that CMS's past approval decisions on new technology add-on payments and commentary support the approval of ENSPRYNG™'s application and stated that CMS appears to be taking a new policy position regarding how an applicant demonstrates substantial clinical improvement. The applicant states that at least one new technology add-on payment applicant, SPRAVATO®, has been approved for new technology add-on payment based on that technology's assertions of improved safety versus other existing treatment options. The applicant also cited six technologies approved for new technology add-on payment that the applicant believes did not submit studies in a manner conducive to a demonstration of improved outcomes over existing FDA-approved treatments or studies with any improved outcomes at all: GIAPREZA™ (83 FR 41342), IMFINZI® (85 FR 58684), ZEMDRI™ (83 FR 41334), BALVERSA™ (84 FR 42242), JAKAFI™ (84 FR 422732), and BLINCYTO™ (80 FR 49451).

Response: We thank the applicant for its comment in response to our concerns and providing additional information for us to consider. After further review, we continue to have concerns as to

[240] Papadopoulos, MC et al. Treatment of neuromyelitis optica: state-of-the-art and emerging therapies. Nat Rev Neurol 2014;10:493–506.

whether ENSPRYNG™ meets the substantial clinical improvement criterion to be approved for new technology add-on payments. Specifically, the applicant did not provide data to demonstrate improved outcomes over existing FDA approved treatments for NMOSD. The applicant commented that the lack of utilization, as evidenced by the absence of claims for SOLIRIS® and UPLIZNA® in the CY 2020 SAF, suggests that the drugs are unavailable in the inpatient setting, and are therefore not the appropriate comparators for ENSPRYNG™. We disagree. Both SOLIRIS® and UPLIZNA® are covered by Medicare, on the market, and, are therefore available for Medicare beneficiaries in the inpatient setting. It appears that the applicant is speculating with regard to the availability of the existing technologies. Therefore, whether there were Medicare claims in the CY 2020 SAF for SOLIRIS® and UPLIZNA® is not relevant to whether these drugs are an appropriate comparator for the purposes of substantial clinical improvement. We further disagree with the applicant that the lack of claims in the CY 2020 SAF data calls into question the degree of clinical improvement with which they are associated. We note that SOLIRIS® demonstrated substantial clinical improvement in their FY 2021 new technology application based on clinical data. We make substantial clinical improvement determinations based on the criteria at § 412.87(b), and not based on the utilization of a technology within the claims data. In addition, while the applicant states that the manufacturer for SPRAVATO asserted without providing supporting data that electroconvulsive therapy (ECT) had limited availability and nevertheless was awarded new technology add-on payments without providing a comparison to that comparator (84 FR 42247 through 42256), we note that we concluded that ECT was not an appropriate comparator because of poor side effects and the clinical challenges and difficulties arising from treatment with ECT which contributed to the limited availability. In this case, we believe that SOLIRIS® and UPLIZNA® do not have limited availability, for the reasons noted previously.

While the commenter is correct that CMS has determined that prior technologies, including GORE TAG® (70 FR 47356 through 47359) and CardioWest ™ (73 FR 48555 through 48557), represented a substantial clinical improvement because they offer a treatment option for patients otherwise ineligible for currently available treatments, we cannot conclude based on the information provided that ENSPRYNG™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. We disagree with the applicant's assertion that individuals who are not currently vaccinated against *Neisseria meningitidis* and patients at a higher risk of PML constitute individual patient populations that are unresponsive to, or ineligible for, currently available treatments. First, vaccinations against *Neisseria meningitidis* are safe and effective, recommended by the CDC,[241] and are required for SOLIRIS® treatment. Individuals that are not vaccinated against Neisseria meningitidis are not considered a separate patient population because eligibility can be easily attained via a widely available vaccine and are also able to receive treatment with UPLIZNA® which does not require a vaccine as noted previously in this section. Second, a patient that is at a higher risk of PML is not ineligible for UPLIZNA®, as the applicant stated, because patients at risk are not contraindicated from using UPLIZNA®, and therefore we conclude that having a higher risk of developing PML does not create a population of patients that are ineligible for UPLIZNA®. As described earlier in this section, we also disagree that patients unwilling or unable to receive an IV infusion constitute a new population. We note that patients with acute NMOSD in the inpatient setting will require IV access for treatment (that is, for IV corticosteroids, plasmapheresis, and/or IST), so we believe that inpatients with NMOSD would not be unwilling or unable to receive further IV therapies. For these reasons, unlike GORE TAG® and CardioWest™ which demonstrated treatment of patients with an unmet need, ENSPRYNG® does not meet this criterion. Please refer to (70 FR 47356 through 47359) and (73 FR 48555 through 48557) for a full discussion of how these determinations were made.

With regard to the applicant's assertion that the self-administration of ENSPRYNG® realizes benefits in the inpatient and outpatient settings, we agree that subcutaneous drugs offer additional flexibility over infusions. The applicant claims that this flexibility may potentially reduce the rate of hospital readmissions, but the applicant did not provide any data to support a reduction of hospitalizations or other outcomes related to the form of drug administration as compared to existing treatments. The applicant listed examples of outcomes that can support a determination of substantial clinical improvement from the regulation text at § 412.87 such as an improvement in quality of life and greater medication adherence or compliance, stating that these are not restricted to demonstration of benefits in the inpatient setting; however, the applicant did not demonstrate that ENSPRYNG® confers these benefits. While we have granted new technology add-on payments to technologies that are given in both the inpatient and outpatient settings, we note that these technologies demonstrated substantial clinical improvement by demonstrating outcomes superior to the standard of care. Please see a full discussion of how these determinations were made at 77 FR 53350 through 53358, 82 FR 38125 through 38129, 84 FR 42201 through 42208, 84 FR 42237 through 42242, 84 FR 42242 through 42247, 84 FR 42256 through 42260, and 85 FR 58672 through 58684.

Finally, we disagree that we are taking a new policy position with regard to how an applicant demonstrates substantial clinical improvement. With all applications, from the time the application is submitted until the final rule, we make a concerted effort to gather all of the information necessary to make an informed decision with regard to substantial clinical improvement. We rigorously review each application with our medical officers and clinical staff to determine whether a technology represents a substantial clinical improvement over existing technologies. We provide concerns in the proposed rule for each technology to ensure transparency with regard to our review, and applicants have the opportunity to address these concerns prior to the final rule in the comment period. With regard to the applicant's reference to other new technology add-on payment applications that were previously approved to demonstrate why ENSPRYNG™ should be approved, we note that every application is evaluated on its own data and merits to determine whether it meets the new technology add-on payment criterion for substantial clinical improvement. In listing examples of various previously approved technologies, it appeared that the applicant did not consider the differences between applications, as well as the variations in currently

[241] CDC, ''Meningococcal: Who Needs to Be Vaccinated?'' *https://www.cdc.gov/vaccines/vpd/mening/hcp/who-vaccinate-hcp.html*, last updated: July 26, 2019.

available technologies an applicant is compared against for purposes of showing substantial clinical improvement. For example, the applicant cited IMFINZI® as an example of a new technology add-on payment approval that, per the applicant, did not submit studies in a manner conducive to a demonstration of improved outcomes over existing FDA-approved treatments or studies with any improved outcomes at all. IMFINZI® was approved for FY 2021 new technology add-on payment after CMS concluded that it met the criteria, including demonstrating a substantial clinical improvement over existing technologies by being one of the first two treatments (the second being TECENTRIQ®, of which the applicant is also the manufacturer) to show improved overall survival in the treatment of patients with extensive-stage small cell lung cancer (ES–SCLC) in more than 20 years (85 FR 58672 through 58684). CMS reached this conclusion after reviewing data submitted by both IMFINZI® and TECENTRIQ® in their applications and during the comment period, including data that showed a sustained overall survival (OS) benefit in combination with SOC chemotherapy as compared to SOC chemotherapy+placebo. CMS did not require the two new treatments to demonstrate superiority over each other as they were determined to be substantially similar. Per our policy, because the applications were submitted for review in the same year, and because we believed they were substantially similar to each other, we considered both sets of clinical data in making a determination, and we did not believe that it would be possible to choose one set of data over another set of data in an objective manner. Accordingly, CMS disagrees with the applicant's claim that CMS approved IMFINZI® without a finding of substantial clinical improvement over existing technologies.

After review of the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for ENSPRYNG™ and consideration of the comments received, for the reasons discussed in the proposed rule and in this final rule, we are unable to determine that ENSPRYNG™ meets the substantial clinical improvement criterion, and therefore we are not approving new technology add-on payments for ENSPRYNG™ for FY 2022.

g. ABECMA® (idecabtagene vicleucel)

Celgene Corporation, a wholly owned subsidiary of Bristol-Myers Squibb (BMS), submitted an application for new technology add-on payment for ABECMA® for FY 2022. ABECMA® is a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell immunotherapy for the treatment of adult patients with relapsed or refractory (RR) multiple myeloma (MM) (RRMM) who have received at least four prior therapies including an immunomodulatory agent (IMiD), a proteasome inhibitor (PI), and an anti-CD38 antibody (for example, triple-class-exposed). ABECMA® is expected to be a 5th line plus (5L+) treatment.

Multiple myeloma (MM) is typically characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. The diagnosis of MM is often suspected because of one (or more) of the following clinical presentations:

- Bone pain with lytic lesions discovered on routine skeletal films or other imaging modalities
- An increased total serum protein concentration and/or the presence of a monoclonal protein in the urine or serum
- Systemic signs or symptoms suggestive of malignancy, such as unexplained anemia
- Hypercalcemia, which is either symptomatic or discovered incidentally
- Acute renal failure with a bland urinalysis or rarely nephrotic syndrome due to concurrent immunoglobulin light chain (AL) amyloidosis

It is important to distinguish MM both from other causes of these clinical presentations and from other plasma cell dyscrasias for the purposes of prognosis and treatment.[242] Data from the US Surveillance, Epidemiology, and End Results (SEER) registry estimate 32,000 new cases of MM and 13,000 deaths from MM annually in the US. This correlates with an annual incidence of approximately 7 per 100,000 men and women per year. MM is largely a disease of older adults. The median age at diagnosis is 65 to 74 years. MM is also slightly more frequent in men than in women (approximately 1.4:1). MM is associated with substantial morbidity and mortality[243] and approximately 25% of patients have a median survival of 2 years or less.[244]

With respect to the newness criterion, ABECMA® received FDA approval on March 26, 2021, and is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. A single dose of ABECMA® contains a cell suspension of 300 to 460 x 106 CAR T-cells.

The applicant submitted a request for unique ICD–10–PCS codes that describe the administration of ABECMA® at the September 2020 Coordination and Maintenance Committee meeting. The following codes were approved to describe procedures involving the administration of ABECMA®: XW033K7 (Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) and XW043K7 (Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7). These codes will be effective starting October 1, 2021.

As previously stated, if a technology meets all three of the substantial similarity criteria as previously described, it would be considered substantially similar to an existing technology and therefore would not be considered ''new'' for purposes of new technology add-on payments.

With respect to whether a product uses the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome, the applicant asserted that ABECMA® does not use the same or similar mechanism of action as other therapies approved to treat 4L+ RRMM or CAR T-cell therapies approved to treat different diseases. According to the applicant, with regard to its mechanism of action, ABECMA® is a chimeric antigen receptor (CAR)-positive T cell therapy targeting B-cell maturation antigen (BCMA), which is expressed on the surface of normal and malignant plasma cells. The CAR construct includes an anti-BCMA scFv-targeting domain for antigen specificity, a transmembrane domain, a CD3-zeta T

[242] Laubauch, J.P. (2021). Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. UptoDate. Available from *https://www.uptodate.com/contents/multiple-myeloma-clinical-features-laboratory-manifestations-and-diagnosis?search=multiple%20myeloma&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.*

[243] R?owan AJ, Allen C, Barac A, et al. Global Burden of Multiple Myeloma: A Systematic Analysis for the Global Burden of Disease Study 2016. JAMA Oncol. 2018;4(9):1221–1227. doi:10.1001/jamaoncol.2018.2128.

[244] Biran, N., Jagannath, S., Risk Stratification in Multiple Myeloma, Part 1: Characterization of High-Risk Disease 2013. Clinical Adv in Hematology & Oncology 11(8); 489–503.

cell activation domain, and a 4–1BB costimulatory domain. Antigen-specific activation of ABECMA® results in CAR-positive T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells.

According to the applicant, with respect to the non-CAR T-cell therapies to treat 4L+ RRMM, specifically Xpovio®, Blenrep, and chemotherapy, ABECMA®'s mechanism of action is different because it is a CAR T-cell therapy. The applicant stated that the mechanism of action for Xpovio® is reversible inhibition of nuclear export of tumor suppressor proteins (TSPs), growth regulators, and mRNAs of oncogenic proteins by blocking exportin 1 (XPO1). XPO1 inhibition by Xpovio® leads to accumulation of TSPs in the nucleus, reductions in several oncoproteins, such as c-myc (a ''master regulator'' which controls many aspects of cellular growth regulation and cellular metabolism) and cyclin D1, cell cycle arrest, and apoptosis of cancer cells. The applicant stated that Blenrep's mechanism of action is cell destruction via microtubule inhibition, where the microtubule inhibitor is conjugated to a BCMA-specific antibody (antibody-drug conjugate). The applicant further stated that the mechanism of action for chemotherapy regimens generally is disruption of normal processes required for cell survival, such as deoxyribonucleic acid (DNA) replication and protein synthesis or degradation.

With respect to the mechanism of action of other currently FDA approved CAR T-cell therapies, according to the applicant, there are no other FDA approved CAR T-cell therapies that are indicated for treatment of RRMM with the same or similar mechanism of action as ABECMA®. The applicant stated that CAR T-cell therapies employ a unique mechanism of action which modifies the patient's own T-cell to express a chimeric antigen receptor (CAR) that programs T-cells to destroy cells that express a specific target. In the case of ABECMA®, this target is BCMA, which is a protein that is highly expressed on the surface of MM cells making it an ideal target for the treatment of MM. The applicant asserted that the key feature that distinguishes ABECMA® from CD–19 directed CAR T-cell therapies is the BCMA targeting domain. According to the applicant, ABECMA®'s BCMA targeting domain means that ABECMA® has a completely different mechanism of action from other currently FDA approved CAR T-cell therapies. In its application, the applicant asserted that since there are currently no FDA approved anti-BCMA CAR T-cell therapies, if approved, ABECMA® is the first CAR T-cell therapy approved for the treatment of RRMM and the only approved CAR T-cell therapy with a BCMA targeting domain which makes it unique as compared to other currently approved FDA therapies used to treat RRMM.

With regard to whether a product is assigned to the same DRG when compared to an existing technology, the applicant stated that it expects that cases involving the administration ABECMA® will be assigned to the same MS–DRG, MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), as other CAR T-cell therapies.

With regard to whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant asserted that, if FDA approved, ABECMA® will be the first and only anti-BCMA CAR T-cell therapy available to treat RRMM. The applicant further asserted that ABECMA® would be indicated for a broader population than other currently FDA-approved available therapies, specifically multiple myeloma patients having received four prior therapies.

In summary, according to the applicant, because ABECMA® has a unique mechanism of action when compared to other currently FDA approved treatments for RRMM, and does not involve the treatment of the same or similar type of disease (RRMM) or the same or similar patient population (triple-class-exposed adult patients with RRMM), the technology is not substantially similar to an existing technology and therefore meets the newness criterion. However, we questioned whether ABECMA®'s mechanism of action may be similar to that of ciltacabtagene autoleucel, another CAR T-cell therapy for which an application for new technology add-on payments was submitted for FY 2022 as discussed in the proposed rule. Both ABECMA® and ciltacabtagene autoleucel seem to be intended for similar patient populations; multiple myeloma patients with three or more prior therapies, and would involve the treatment of the same conditions; adult patients with relapsed or refractory multiple myeloma.

We indicated that we were interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion, to inform our analysis of whether ABECMA® and ciltacabtagne autoleucel, if approved by July 1, 2021, are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We invited public comments on whether ABECMA® is substantially similar to an existing technology and whether it meets the newness criterion.

Comment: A few commenters encouraged CMS to consider assigning new technology add-on payments for new CAR T-cell therapies including idecabtagene vicleucel to ensure patient access.

Another commenter disagreed with CMS that ABECMA® would not be considered ''new'' for purposes of new technology add-on payment. The commenter supported that this product is different from the currently approved products treating patients with multiple myeloma and therefore supported that ABECMA® receive new technology add-on payment status.

Response: We appreciate the input from the commenters and the information they have highlighted, and we have taken these comments into consideration in our final decision, which is discussed later in this section.

Comment: In response to CMS' concerns for the substantial similarity criterion, the applicant submitted a comment. The applicant asserted that ABECMA® is currently the only FDA approved CAR T-cell therapy for the treatment of adult patients with RRMM after four or more prior lines of therapy and the only CAR T-cell therapy approved for the treatment of multiple myeloma. The applicant stated that unlike other therapies approved to treat 5L+ RRMM, ABECMA® modifies the patient's own T-cell to express a CAR that programs T-cells to kill cells that express a specific target, the BCMA. According to the applicant, all other approved CAR T-cell therapies today target the CD19 cell surface protein and are approved for the treatment of specific types of Non-Hodgkins Lymphoma (NHL).[245] The applicant asserted that ABECMA® does not involve the treatment of the same or similar type of disease or the same or similar patient population when compared to existing technology because ABECMA® is the only CAR T-cell therapy available for the treatment of patients with RRMM. The applicant stated that the other treatments used in this space utilize different technologies, including small molecule inhibitors of

[245] Nair, R. and J. Westin, CAR T cells. Adv Exp Med Biol, 2020. 1244: p. 215–233.

cellular processes (XPOVIO®) or antibody drug conjugates (BLENREP).[246]

In regard to CMS' concern whether ABECMA® and ciltacabtagne autoleucel are similar, the applicant commented that ciltacabtagene autoleucel is not yet FDA approved and is unlikely to be FDA approved by July 1, 2021, as its FDA Prescription Drug User Fee Act target action date has been set for November 29, 2021.[247] The applicant stated that CMS should evaluate ABECMA®'s new technology add-on payment application on its own and should grant new technology add-on payment status effective October 1, 2021, in order to ensure Medicare beneficiary access.

Response: After consideration of the public comments we received and information submitted by the applicant in its application, we agree with the applicant that ABECMA® is not used to treat the same or similar type of disease (for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody) or a similar patient population as currently available treatment options, and that ABECMA® does not use the same or similar mechanism of action as other technologies used for the treatment of the indication stated previously. Furthermore, as previously noted, the applicant for ciltacabtagene autoleucel withdrew its application prior to the issuance of this FY 2022 IPPS/LTCH PPS final rule, and we further note that the technology as not yet been FDA approved as of the time of the development of this final rule. We believe that the ABECMA® has a new mechanism of action as it is the only CAR T-cell therapy available for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody and, therefore, we believe that ABECMA® is not substantially similar to existing technologies and meets the newness criterion. We consider the beginning of the newness period to commence on the first date ABECMA® received FDA approval, March 26, 2021.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR correction notice (December 1, 2020) file to identify potential cases representing patients who may be eligible for treatment using ABECMA®. In its analysis, the applicant identified a primary cohort to assess whether this therapy met the cost criterion. The following ICD–10–CM diagnosis codes were used to identify claims involving multiple myeloma procedures.

ICD-10-CM Code	Code Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

The applicant chose to limit its analysis to MS–DRG 016 (Autologous Bone Marrow Transplant W CC/MCC or T-Cell Immunotherapy, MS–DRG 840 (Lymphoma & Non-Acute Leukemia W MCC) and MS–DRG 841 (Lymphoma & Non-Acute Leukemia W CC). The claim search conducted by the applicant resulted in 1,955 claims mapped to MS–DRG 016, MS–DRG 840 and MS–DRG 841 using the FY 2019 MedPAR. The applicant determined an average unstandardized case weighted charge per case of $1,237,393. The applicant used the MS–DRG–018 New Technology Threshold for FY 2022 from the FY 2021 IPPS/LTCH PPS final rule.

The applicant removed all charges in the drug cost center for the prior technology because, according to the applicant, it is not possible to differentiate between different drugs on inpatient claims. The applicant added that this is likely an overestimate of the charges that would be replaced by the use of ABECMA®. The applicant then standardized the charges using the FY 2019 final rule impact file. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the new technology, the applicant used a national average CCR for the CAR T-cell therapies of 0.295. To determine this alternative CCR for CAR T-cell therapies, the applicant referred to the FY 2021 IPPS/LTCH PPS final rule AOR/BOR file and calculated an alternative markup percentage by dividing the AOR drug charges within DRG 018 by the number of cases to determine a per case drug charge. The applicant then divided the drug charges per case by $373,000, the acquisition cost of YESCARTA and KYMRIAH. The applicant calculated a final inflated average case-weighted standardized charge per case of $1,329,540, which exceeded the average case-weighted threshold amount of $1,251,127 by $78,413. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

As noted in previous discussions, the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy. Therefore, with regard to the use of this data for purposes of calculating a CAR T-cell CCR, we stated in the proposed rule that we were uncertain how representative this data is for use in the applicant's cost analyses given the potential for variability.

We stated that we continued to be interested in public comments regarding the eligibility of CAR T-cell technologies for new technology add-on payments when assigned to MS–DRG 018. As we have noted in prior rulemaking with regard to the CAR T-cell therapies (83 FR 41172 and 85 FR 58603 through 58608), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act,

[246] Chari, A., et al., Oral Selinexor-Dexamethasone for Triple-Class Refractory Multiple Myeloma. N Engl J Med, 2019. 381(8): p. 727–738; Lonial, S., et al., Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM–2): A two-arm, randomised, open-label, phase 2 study. Lancet Oncol, 2020. 21(2): p. 207–221.

[247] ''U.S. Food and Drug Administration Grants BCMA CAR–T Cilta-cel Priority Review for the Treatment for Relapsed/Refractory Multiple Myeloma.'' Legend Biotech Corporation, May 26, 2021. Press release.

there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act.

We invited public comment on whether ABECMA® meets the cost criterion.

Comment: We received a comment from MEDPAC which addressed the cost criterion in general as it relates to CAR T-cell therapies. Please refer to the response in the BREYANZI® application in section II.F.X.c. of the preamble of this final rule for detailed discussion of this issue.

Comment: We received multiple comments in response to our concern for CAR T-cell therapy, the MS–DRG 018 assignment, and new technology add-on payment eligibility.

Response: For a complete discussion of these comments and our response, please see the BREYANZI® application in section II.F.X.c. of the preamble of this final rule.

Comment: A few commenters suggested that CMS should establish a new technology add-on payment pathway specific to gene therapies similar to that of the QIDP and breakthrough device designation. These commenters suggested that these new pathways will provide streamlined opportunities for novel therapies to receive new technology add-on payment under the IPPS. Some commenters stated that CMS should create a category such as Regenerative Medicine Advanced Therapy (RMAT) designation to meet the newness and substantial clinical improvement new technology add-on payment criteria.

Response: We did not propose to add a new pathway to the new technology add-on payment evaluation process. We believe this comment is outside the scope of this rule.

Comment: In response to CMS' concerns, the applicant submitted similar comments to those submitted by the applicant for BREYANZI®. As discussed previously, the applicant stated in its comment that CAR T-cell therapies that meet the cost and other criteria for new technology add-on payment status should continue to be eligible for new technology add-on payment status notwithstanding the creation of MS–DRG 018. The applicant stated that there is still a need for new technology add-on payment status for new CAR T-cell therapies, like ABECMA®, to ensure patient access. Further, the applicant stated while the payment amount for MS–DRG 018 is certainly more aligned with CAR T-cell therapy costs generally, ABECMA® exceeds the cost threshold for MS–DRG 018, meaning that the reimbursement rate for MS–DRG 018 is not adequate for ABECMA®. The applicant asserted that per CMS, this is precisely the type of scenario that the new technology add-on payment is intended to address.

In responses to CMS' concerns regarding the cost criterion and the variability of provider billing and charging practices for CAR T-cell therapies (86 FR 25258), the applicant stated they considered the variability of CAR T-cell charging practices when developing its cost analyses and presented options that were intended to address this variability by using more conservative assumptions than have typically been the case for other new technology add-on payment applications. The applicant stated that most new technology add-on payment applications use the national average CCR for the cost center for which the new technology belongs is used to inflate the acquisition cost for the new technology to charges. The applicant added that in the case of a drug or biological, this would mean that the inverse of the national average CCR for drugs would be used to convert the WAC of ABECMA® to charges. The applicant stated that using the pharmacy CCR in the prescribed manner would result in charges that would potentially overstate actual hospital charging practices for CAR T-cell therapies. Furthermore, the applicant noted that numerous studies on charge compression have shown that hospital charging practices tend to result in higher markup percentages for lower cost drugs and lower markup percentages for higher cost drugs. The applicant added that given that the WAC for ABECMA® is well above the average of drugs overall, they were concerned that using the inverse of the national average drug CCR might overstate what hospitals would typically charge for ABECMA® on inpatient claims. Therefore, the applicant calculated a CAR T-cell specific CCR based solely on the total drug charges for CAR T-cell claims.

The applicant stated that to calculate the CAR T-cell CCR, they took the total drugs charges for cases in MS–DRG 018 from the FY 2021 IPPS/LTCH PPS final rule After Outliers Removed/Before Outliers Removed (AOR/BOR) file ($183,433,947.58). Next, the applicant divided that amount by the number of cases (145) to determine an average drug charge per case ($1,265,061.70). The applicant then divided that amount by $373,000, the acquisition cost of YESCARTA® and KYMRIAH®. This value represents the average mark-up percentage hospitals used to convert the cost of CAR T-cell therapy to charges on claims in FY 2019. The applicant converted this mark-up percentage to a CCR by dividing 1 by the percentage (1/3.39 = 0.295).

Ultimately, the applicant stated that it recognizes CMS's concern that hospitals vary in their CAR T-cell charging practices but states their method for calculating a CAR T-cell specific CCR is meant to address this exact concern. The applicant asserted that by focusing solely on CAR T-cell claims, they are able to capture the range of charging practices in hospitals that used a CAR T-cell therapy in a non-clinical trial case in 2019. Furthermore, the applicant stated that in addition to addressing the concerns about variability in hospital charging practices, the CAR T-cell CCR is also a more conservative assumption to use in the cost threshold analysis because it inflates CAR T-cell costs to charges at a lower percentage (339%) than if the inverse of the national average drug CCR is used (535%).

Response: We appreciate the information provided by the applicant in their comment in regard to their calculation of a CAR T-cell CCR. As we stated in section E.2.b. of this rule, we continue to believe that it is premature to make structural changes to the IPPS at this time to pay for CAR T-cell therapies (78 FR 58453). As we gain more experience paying for these therapies under the IPPS, we may consider these comments to inform future rulemaking. However, we appreciate the thoughtfulness used by the applicant to provide as clear as possible a description of CAR T-cell therapy cost calculations. We appreciate the usage of multiple cost analyses, such as varying the CCR used to inflate cost to charges, which potentially allowed for a more conservative markup.

After consideration of the public comments we received and based on the information included in the applicant's new technology add-on payment application, we believe that the ABECMA® system meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that it believes that ABECMA® represents a substantial clinical improvement over existing technologies because: (1) The totality of the circumstances regarding ABECMA®'s clinical efficacy, safety, and data make clear that ABECMA® substantially improves, relative to services or technologies currently available, the treatment of Medicare beneficiaries with RRMM; (2) ABECMA® has superior effectiveness compared to existing therapies; (3) ABECMA® fills an unmet need as demonstrated by the patient population in its registrational study,

which is reflective of real-world RRMM patients and 4) ABECMA® improves quality of life for patients with RRMM.

In support of its assertion that the totality of the circumstances regarding ABECMA®'s clinical efficacy, safety, and data make clear that ABECMA® substantially improves, relative to services or technologies currently available, the treatment of Medicare beneficiaries with RRMM, the applicant cited results from the KarMMA study, a single-arm, open-label, phase 2 trial of ABECMA®. The primary outcome measure for the KarMMA study was overall response rate (ORR). Secondary endpoints were; complete response rate (CRR) (key secondary; null hypothesis ≤10%), safety, duration of response (DOR), progression-free survival (PFS), overall survival (OS), pharmacokinetics (PK), minimum residual disease (MRD), quality of life (QOL) and health economics and outcomes research (HEOR). The study enrolled 140 patients and 128 received treatment. Patients were treated at target dose between 150 and 450×10^6 CAR T-cells. Treated patients had received three or more prior lines of therapy including an immunomodulatory drug (IMiD), a proteasome inhibitor (PI), and an anti-CD38 antibody. All patients were refractory to the last regimen (94% were refractory to anti-CD38 and 84% were refractory to triple therapy). Efficacy results showed an ORR of 50% for patients (n=4) receiving the target ABECMA® dose of 150×10^6; 68.6% for patients (n=70) receiving the target dose of 300×10^6; 81.5% for patients (n=54) receiving the target dose of 450×10^6. The overall ORR for all patients (n=128) who received ABECMA® was 73.4%.

The applicant asserts that in the KarMMA study, patients who received ABECMA® achieved numerically superior response rates, duration of response, and overall survival compared with outcomes seen for alternative therapies (belantamab-mafodotin and selinexor) in other trials.[248] [249] [250] [251] [252] [253] Response rates, according to the applicant, were also high even in patients refractory to five therapies (defined as 2 IMiD agents, 2 PIs, and 1 anti-CD38 antibody), reflecting the novel mechanism of action, according to the applicant. The applicant asserts that compared with anti-CD–19 CAR T-cell therapies, the adverse event profile revealed low rates of grade 3+ CRS (5%) and neurotoxicity (NT) (3%).[254] According to the applicant, these safety results confirm that ABECMA® has the potential to offer a meaningful benefit to Medicare beneficiaries. The applicant also asserts that ABECMA® has been demonstrated to be effective and with a manageable safety profile for patients with a high-unmet need (older age, aggressive disease). The applicant asserts that the results from the pivotal KarMMa study confirm the clinical benefit of ABECMA® in a heavily pre-treated RRMM patient population.

We noted in the proposed rule that in contrast with anti-CD–19 CAR T-cell therapies (for leukemia or lymphoma) where a high fraction of responders remained in remission even after 5 years, ABECMA® does not appear to result in long-term remission. In the KarMMA study, among responding patients, over 75% relapsed by 20 months, with no plateauing of the response curve.[255]

To support its assertion that ABECMA® has superior effectiveness compared to existing therapies, the applicant provided results from the KarMMa-RW study,[256] a single-arm, open-label, phase 2 trial, examining real-world treatment patterns in heavily pretreated patients with RRMM. The study also provides a comparison against outcomes in the KarMMa study. The KarMMa-RW study was conducted to assess treatment patterns in real-world RRMM patients with characteristics similar to the KarMMa population and to compare outcomes with currently available therapies in this synthetic cohort vs ABECMA® therapy in the KarMMa study. The primary endpoint of the KarMMA–RW study was overall response rate (ORR). Secondary endpoints of the study were complete response rate (CRR), very good partial response (VGPR) rate, progression free survival (PFS) and overall survival (OS). Subgroup analyses by age, sex, double-class refractory (IMiD agents and PIs) and number of prior anti-myeloma regimens per year (≤1 per year or >1) were conducted to compare ORR and PFS between the KarMMa cohort and eligible RRMM cohort. Since complete response assessment requires a bone marrow biopsy evaluation, per International Myeloma Working Group (IMWG) uniform response criteria for multiple myeloma, when data to assess a complete response were not available in eligible RRMM cohort, analyses were summarized for VGPR or better (≥VGPR) to avoid underestimating the response in the eligible RRMM cohort.

Of 1,949 real-world RRMM patients, 1,171 were refractory to their last treatment regimen at baseline. Patients who had exposure to any BCMA-directed therapy or gene-modified therapy were excluded. Of the 1,171 patients in the refractory RRMM cohort, 528 received the next line of therapy; 643 patients were excluded due to no new treatment due to death (n = 441) and no new treatment due to no follow-up (n = 202). Of the remaining 528 patients, 190 triple class exposed patients were selected as the eligible RRMM cohort based on the KarMMa eligibility criteria. The ORR in the KarMMa and eligible RRMM cohorts was 76% and 32% (p = <0.0001), respectively. The VGPR in the KarMMa and eligible RRMM cohorts was 57% and 14% (p = <0.0001), respectively.

A matched-paired analysis was conducted and ORR was adjusted for matching. Results from the matched-paired analysis were consistent with the primary analysis: the ORR for the matched KarMMa cohort (n=76–80) and matched eligible RRMM (n=76–80) was 72% and 29% (p = <0.0001), respectively. According to the applicant, PFS was significantly improved in KarMMa vs the eligible RRMM cohort; median PFS was 11.3 months and 3.5 months in the KarMMa and Eligible

[248] Munshi NC, Anderson, Jr LD, Shah N, et al. Idecabtagene vicleucel (ide-cel; bb2121), a BCMA-targeted CAR T-cell therapy, in patients with relapsed and refractory multiple myeloma (RRMM): Initial KarMMa results. J Clin Oncol. 2020;38(15_suppl):8503–8503. doi:10.1200/JCO.2020.38.15_suppl.8503.

[249] Rodriguez-Otero P, Weisel K, Davies F, et al. Matching-adjusted indirect comparisons of efficacy outcomes for idecabtagene vicleucel from the KARMMA study vs selinexor plus dexamethasone (STORM part 2) and belantamab mafodotin (DREAMM–2). In: European Hematology Association. ; 2020.

[250] Jagannath S, Lin Y, Goldschmidt H, et al. KarMMa-RW: A study of real-world treatment patterns in heavily pretreated patients with relapsed and refractory multiple myeloma (RRMM) and comparison of outcomes to KarMMa. J Clin Oncol. 2020;38(15_suppl):8525–8525. doi:10.1200/jco.2020.38.15_suppl.8525.

[251] Raje N, Berdeja J, Lin Y, et al. Anti-BCMA CAR T-cell therapy bb2121 in relapsed or refractory multiple myeloma. N Engl J Med. 2019;380(18):1726–1737. doi:10.1056/NEJMoa1817226.

[252] Lonial S, Lee HC, Badros A, et al. Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM–2): A two-arm, randomised, open-label, phase 2 study. Lancet Oncol. 2020;21(2):207–221. doi:10.1016/S1470–2045(19)30788–0.

[253] Chari A, Vogl DT, Gavriatopoulou M, et al. Oral Selinexor–Dexamethasone for Triple-Class Refractory Multiple Myeloma. N Engl J Med. 2019;381(8):727–738. doi:10.1056/nejmoa1903455.

[254] Munshi NC, Anderson, Jr LD, Shah N, et al. Idecabtagene vicleucel (ide-cel; bb2121), a BCMA-targeted CAR T-cell therapy, in patients with relapsed and refractory multiple myeloma (RRMM): Initial KarMMa results. *J Clin Oncol.* 2020;38(15_suppl):8503–8503.

[255] Ibid.

[256] Jagannath S, Lin Y, Goldschmidt H, et al. KarMMa-RW: A study of real-world treatment patterns in heavily pretreated patients with relapsed and refractory multiple myeloma (RRMM) and comparison of outcomes to KarMMa. *J Clin Oncol.* 2020;38(15_suppl):8525–8525.

RRMM cohorts, respectively (p = <0.0001). Median follow-up was 11.3 months (KarMMa) and 10.2 months (eligible RRMM cohort) at data cutoff. According to the applicant, OS was significantly improved in KarMMa vs the eligible RRMM cohort. OR was 18.2 months for the KarMMa cohort (across all target doses from 150–450 $\times 10^6$ CAR T-cells) and 14.7 months for the eligible RRMM cohort. The estimated 12-month probability of surviving was 80% in the KarMMa cohort and 56% in the eligible RRMM cohort. Median follow-up was 12.0 months (KarMMa) and 15.0 months (eligible RRMM cohort) among surviving patients at data cutoff.

The applicant asserts that the results from the KarMMa-RW study confirm that there is no clear standard of care for RRMM patients who received at least 3 prior therapies, including IMiD agents, PIs, and anti-CD38 antibodies. Patients in the eligible RRMM cohort received 94 different treatment regimens as next-line therapy and according to the applicant, outcomes were sub-optimal with currently available therapies in the real-world RRMM patients. The applicant asserts that significantly improved outcomes were demonstrated with ABECMA® treatment in the KarMMa cohort vs the similar real-world population (eligible RRMM cohort). The applicant noted that the real world myeloma patient population is older (MM incidence is known to increase with age, with over 60 percent of all new cases occurring in adults aged 65+years).[257] The applicant asserts that results were consistent across subgroups including patients aged ≥ 65 years.

The applicant also provided a comparison of the efficacy of ABECMA® and Xpovio® from the STORM study and Blenrep from the DREAMM–2 study. STORM is a prospective, multicenter phase 2 study of Xpovio® and dexamethasone in patients with RRMM (n = 122) in the 4L+ setting. The STORM trial served as the basis for regulatory approval in the US and demonstrated the clinical efficacy and safety of Xpovio®. The ORR was 26% for patients in the STORM study vs 73% for patients treated with ABECMA® in the KarMMa study, CR was 1% for patients in the STORM study vs 33% for patients treated with ABECMA® in the KarMMa study, medium duration of response (mDOR) was 4.4 months for patients in the STORM study vs 10.7 months for patients treated with ABECMA® in the KarMMa study, and PFS was 3.7 months for patients in the STORM study vs 8.8 months for patients treated with ABECMA® in the KarMMa study. The DREAMM–2 study is a prospective, multicenter Phase 2 study of Blenrep in patients with RRMM (n = 122) in the 4L+ setting. The ORR was 31% for patients in the DREAMM–2 study vs 73% for patients treated with ABECMA® in the KarMMa study, CR was 3% for patients in the DREAMM–2 study vs 33% for patients treated with ABECMA® in the KarMMa study, medium duration of response (mDOR) was not reached in the Blenrep group whereas it was 10.7 months for patients treated with ABECMA® in the KarMMa study, and PFS was 2.9 months for patients in the DREAMM–2 study vs 8.8 months for patients treated with ABECMA® in the KarMMa study.

Because ABECMA® showed improved ORR, CR, medDOR and PFS when compared to Xpovio® and Blenrep, the applicant asserts that ABECMA® provides a substantial clinical improvement over these existing therapies.

To support that ABECMA® fills an unmet need as demonstrated by the patient population in its registrational study, the Phase 2 KarMMa study, the applicant asserted that in addition to showing deep and durable responses and a manageable safety profile in heavily pretreated, highly refractory RRMM patients in the context of controlled clinical studies, comparisons of outcomes in real world patients (that is, patients not enrolled in clinical trials) support the assertion that ABECMA® offers significantly improved outcomes for RRMM compared with currently available therapies. The applicant asserted that when compared to myeloma patients generally included in clinical studies, the real world myeloma patient population is older (MM incidence is known to increase with age, with over 60 percent of all new cases occurring in adults aged > 65years)[258] and sicker (due to the high proportion of elderly patients in this population, those with MM commonly also have additional comorbidities associated with increased age, including conditions such as osteoporosis, arthritis, diabetes, additional malignancies, cardiovascular disease, and renal dysfunction, amongst others).[259] The applicant provided an abstract from the MAMMOTH study, a noninterventional, retrospective cohort analysis conducted to assess outcomes in patients after they become refractory to anti-CD38 monoclonal antibodies, including a subset of patients who were triple-class-exposed. Patients in STORM (analyzing Xpovio® plus dexamethasone) had an ORR of 32.8% versus 25% for patients receiving conventional care in MAMMOTH (p=0.078) and STORM patients had better OS than patients in MAMMOTH (median 10.4 vs 6.9 months) (p=0.043). The applicant asserts that these results highlight a high unmet need in a patient population refractory to anti-CD38 monoclonal antibody, including a subset of triple-class exposed patients.

To support the assertion that ABECMA® improves quality of life for patients with RRMM, the applicant referenced ABECMA®'s impact on Health-related quality of life (HRQoL) as assessed in the KarMMa study as a secondary endpoint. HRQoL was assessed using the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life C30 Questionnaire (QLQ–C30) and the EORTC Multiple Myeloma Module (MY20). The QLQ–C30 consists of 30 questions addressing 5 functional domain scales, 3 symptom scales, a Global health/QoL scale, and 6 single item measures.[260] The QLQ–MY20 consists of 20 questions addressing 4 myeloma-specific HRQoL domains (disease symptoms, side effects of treatment, future perspectives, and body image). Primary subscales of interest were QLQ–C30 Fatigue, Pain, Physical Functioning, Cognitive Functioning, and Global Health/QoL subscales and QLQ–MY20 Symptom and Side Effects subscales. Subscales were preselected based on their relevance to this patient population. The data are based on a minimum of 10 months post-infusion. Median follow-up durations at the target dose levels of 150, 300, and 450 $\times 10^6$ CAR T-cells were 17.8, 13.9, and 9.7 months, respectively. Of 140 patients enrolled in KarMMa, 128 received ABECMA®, of whom 121 (94.5%) and 120 (93.8%) were evaluable for HRQoL by QLQ–C30 and QLQ–MY20, respectively. At baseline, ABECMA®-treated patients had less favorable scores for all QLQ–C30 domains of interest (fatigue, pain, Global Health/QoL, physical functioning and cognitive functioning) than the general population. From baseline at multiple

[257] Cancer Stat Facts: Myeloma, NCI SEER, *https://seer.cancer.gov/statfacts/html/mulmy.html* (last visited October. 7, 2020).

[258] Cancer Stat Facts: Myeloma, NCI SEER, *https://seer.cancer.gov/statfacts/html/mulmy.html* (last visited Oct. 7, 2020).

[259] Hari P et al. The impact of age and comorbidities on practice patterns and outcomes in patients with relapsed/refractory multiple myeloma in the era of novel therapies. Journal of Geriatric Oncology. 2018;9(2):138–144 (Hari, 2018).

[260] Helena Maes & Michel Delforge (2015) Optimizing quality of life in multiple myeloma patients: current options, challenges and recommendations, Expert Review of Hematology, 8:3, 355–366, DOI: 10.1586/17474086.2015.1021772

time points through month 9 post-infusion, the applicant asserts that clinically meaningful improvements were observed in QLQ–C30 Fatigue, Pain, Physical Functioning, and Global Health subscale scores relative to baseline, as the mean score from baseline showed improvement in all domains. The applicant asserts that these results support that ABECMA® provides meaningful improvements in HRQoL and self-reported symptoms associated with heavily pretreated RRMM and demonstrate that ABECMA® provides meaningful improvement in both global function and symptoms related to MM.

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for ABECMA®, we stated in the proposed rule that we questioned whether, due to the lack of randomization, there is sufficient evidence to establish the efficacy of ABECMA® compared with current alternatives. We stated that it is unknown whether the superior outcomes for ABECMA® in the KarMMA study, which we stated has not been peer-reviewed, were due to more effective therapy or other factors, such as differences in patient population or treating oncologist. We also noted that the applicant chose to use ORR data as a measure of substantial clinical improvement rather than the more clinically relevant and available OS data.

We invited public comment on whether ABECMA® meets the substantial clinical improvement criterion.

Comment: In response to CMS' concerns regarding the substantial clinical improvement criterion, the applicant submitted a comment stating that ABECMA® is a substantial clinical improvement over existing technologies because: (1) The totality of the circumstances regarding ABECMA®'s clinical efficacy, safety, and data make clear that ABECMA® substantially improves, relative to services or technologies currently available, the treatment of Medicare beneficiaries with RRMM; (2) ABECMA® has superior effectiveness compared to existing therapies; (3) ABECMA® fills an unmet need as demonstrated by the patient population in its registrational study, which is reflective of real-world RRMM patients, and (4) ABECMA® improves quality of life for patients with RRMM.

The applicant stated that it is essential for CMS to recognize that multiple myeloma is a different disease from NHL, where CD–19 CAR T directed therapies are approved.[261] The applicant added multiple myeloma is a disease characterized by persistence of residual disease and multiple periods of remission and relapse, with cure not generally achieved by conventional therapies.[262] The applicant added that only long-term follow-up data will definitively show if a plateau in survival occurs after BCMA directed CAR T-cell treatment and that the KarMMA study presented data after a median follow up of 13.3 months.

The applicant stated that they believe it is not appropriate to compare outcomes between different CAR T-cell therapies approved and studied in patients with completely different diseases where the most appropriate comparison is between treatments indicated for the same patient population and disease. According to the applicant, the updated results, after a median follow up of 24.8 months, from the pivotal KarMMa study demonstrated outcomes remained consistent with those initially reported.[263] The applicant stated that the CR/sCR rate remained 33% across all doses studied with an estimated median PFS was 8.6 months for all patients and 12.2 months for patients treated at the 450×106 dose; for the 33% of patients on the KarMMa study who had a CR/sCR, the median duration of response increased to 20.2 months.[264]

The applicant disagreed with CMS's concerns surrounding the lack of randomization, peer-review status, and use of ORR as a measure of substantial clinical improvement. The applicant states that the results from the KarMMa study, which supported the FDA approval of ABECMA®, were published February 2021 in the New England Journal of Medicine.[265]

The applicant stated that the KarMMa study, while using ORR as a primary endpoint, also demonstrated improvements in complete response (CR) rate, duration of response, PFS and OS compared with conventional therapies. The applicant stated that two analyses compared patients enrolled in the KarMMa clinical study to similar patients treated with conventional therapy enrolled on other observational studies: MAMMOTH[266] [267] in which a matched adjusted indirect comparison (MAIC) demonstrated that ABECMA® offers statistically significant, clinically meaningful improvements in ORR, OS, and PFS when compared with conventional care and regimens, and KarMMa-RW in which the median progression free survival was observed to be higher in the KarMMa group at 11.3 versus 3.5 months in the similar RW cohort and overall survival 18.2 versus 14.7 months, respectively.

The applicant concluded that the totality of the clinical efficacy and safety data from the prescribing information demonstrates that ABECMA® has equal or better efficacy and a better safety profile than existing therapeutic alternatives in a broad RRMM patient population, including patients aged 65+ years. Based on an updated analysis of overall survival for patients, the applicant asserts that after a median follow up of 24.8 months, 51% of patients remain alive two years after treatment with ABECMA® with an estimated median OS of 24.8 months.[268] According to the applicant, median survival expectation with conventional therapies in this heavily pre-treated patient population (median 6 (3–16) prior lines), 94% refractory to anti-CD38 antibody, 84% refractory to all three of the main classes of antimyeloma drugs) is estimated at 9.3 months.[269] Therefore

[261] Nair, R. and J. Westin, CAR T cells. Adv Exp Med Biol, 2020. 1244: 215–233.

[262] Kumar, S.K., et al., Multiple myeloma. Nat Rev Dis Primers, 2017. 3: 17046; Rajkumar, S.V. and S. Kumar, Multiple Myeloma: Diagnosis and Treatment. Mayo Clin Proc, 2016. 91(1): 101–19.

[263] Larry D. Anderson, J., Nikhil C. Munshi, Nina Shah, Sundar Jagannath, Jesus G. Berdeja, Sagar Lonial, Noopur S. Raje, David S. Siegel, Yi Lin, Albert Oriol, Philippe Moreau, Ibrahim Yakoub-Agha, Michel Delforge, Fabio Petrocca, Payal Patel, Liping Huang, Timothy B. Campbell, Kristen Hege, Jesús F. San-Miguel, Idecabtagene vicleucel (ide-cel, bb2121), a BCMA-directed CAR T cell therapy, in relapsed and refractory multiple myeloma: Updated KarMMa results. ASCO 2021 Conference Proceedings, 2021: 8016.

[264] Munshi, N.C., et al., Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. New England Journal of Medicine, 2021. 384(8): p. 705–716.

[265] Munshi, N.C., et al., Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. New England Journal of Medicine, 2021. 384(8): p. 705–716.

[266] Gandhi, U.H., et al., Outcomes of patients with multiple myeloma refractory to CD38-targeted monoclonal antibody therapy. Leukemia, 2019. 33(9): 2266–2275.

[267] Shah, N., et al., A Matching-Adjusted Indirect Comparison of Efficacy Outcomes for Idecabtagene Vicleucel (ide-cel, bb2121), a BCMA-Directed CAR T Cell Therapy Versus Conventional Care in Triple-Class-Exposed Relapsed and Refractory Multiple Myeloma. Blood, 2020. 136 (Supplement 1): 6–7.

[268] Larry D. Anderson, J., Nikhil C. Munshi, Nina Shah, Sundar Jagannath, Jesus G. Berdeja, Sagar Lonial, Noopur S. Raje, David S. Siegel, Yi Lin, Albert Oriol, Philippe Moreau, Ibrahim Yakoub-Agha, Michel Delforge, Fabio Petrocca, Payal Patel, Liping Huang, Timothy B. Campbell, Kristen Hege, Jesús F. San-Miguel, Idecabtagene vicleucel (ide-cel, bb2121), a BCMA-directed CAR T cell therapy, in relapsed and refractory multiple myeloma: Updated KarMMa results. ASCO 2021 Conference Proceedings, 2021: 8016.

[269] Larry D. Anderson, J., Nikhil C. Munshi, Nina Shah, Sundar Jagannath, Jesus G. Berdeja, Sagar Lonial, Noopur S. Raje, David S. Siegel, Yi Lin, Albert Oriol, Philippe Moreau, Ibrahim Yakoub-

the applicant asserted ABECMA® is clearly a substantial clinical improvement over alternative therapies for patients with RRMM after four or more prior lines of therapy.

Response: We appreciate the information provided by the applicant in their public comment. Based on the additional information received, we agree that ABECMA® represents a substantial clinical improvement over existing technologies for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. We believe that the updated analysis information provided by the applicant demonstrated statistically significant and clinically meaningful improvements in ORR, OS, and PFS for patients treated with ABECMA®. We also agree with the applicant that ABECMA® fills an unmet need in the 4L+ treatment of RRMM as it offers a treatment option for patients unresponsive to currently available therapies.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that ABECMA® meets the criteria for approval of the new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2022. Cases involving the use of ABECMA® that are eligible for new technology add-on payments will be identified by procedure codes XW033K7 (Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) or XW043K7 (Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7).

In its application, the applicant estimated that the cost of ABECMA® is $419,500.00 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of ABECMA® is $272,675.00 for FY 2022.

h. INDIGO Aspiration System With Lightning Aspiration Tubing

Penumbra, Inc. submitted an application for the INDIGO® Aspiration System with Lightning Tubing (''INDIGO® with Lightning'') for FY 2022. Per the applicant, INDIGO® with Lightning is a mechanical thrombectomy aspiration system used in the treatment of pulmonary embolism, deep vein thrombosis and peripheral arterial thromboembolism that optimizes thrombus removal by differentiating between thrombus and blood.

According to the applicant, INDIGO® with Lightning performs clot detection and removal via smart technology which enables the physician to determine when the catheter is in thrombus and when it is in patent flow resulting in blood loss reduction through intermittent aspiration mechanical thrombectomy. The applicant stated that INDIGO® with Lightning is used for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism. The applicant stated that the INDIGO® with Lightning is composed of a mechanical thrombectomy aspiration pump (known as the Penumbra Engine) that is packaged with INDIGO® CAT12 (12 French) and CAT8 (8 French) catheters as well as Lightning, a clot detection/blood loss reduction technology embedded in the Penumbra Engine pump and tubing.

Arterial thromboembolism can result in acute limb ischemia (ALI) which requires emergent treatment. Venous thromboembolism is a condition which includes both deep vein thrombosis (DVT) and pulmonary embolism (PE) and occurs in 1 to 2 individuals per 1000 per year and is predominantly a disease of older age.[270] The 2020 American Society of Hematology guidelines for venous thromboembolism include recommendations for the treatment of patients with both pulmonary embolism and deep vein thrombosis, and recommended treatments include home care, systemic pharmacological thrombolysis, and procedural care.[271]

Procedural care may include open procedures as well as catheter-directed thrombolysis and percutaneous mechanical thrombectomy.[272] In catheter-directed thrombolysis, a thrombolytic agent is infused intravascularly adjacent to the clot burden through a percutaneous transcatheter.[273] In percutaneous mechanical thrombectomy, the thrombus is lysed or removed mechanically. The therapies may be used separately or in conjunction with one another.[274]

The applicant stated that mechanical thrombectomy may be performed with a variety of devices. These methods include aspiration thrombectomy, rheolytic thrombectomy, and fragmentation thrombectomy.[275]

The applicant stated that INDIGO® with Lightning differs from other mechanical thrombectomy devices on the basis of the use of a mechanical pump to generate a vacuum for aspiration and ''intelligent aspiration'' which differentiates clots and patient blood flow, thereby limiting blood loss. The applicant states that other endovascular mechanical thrombectomy devices do not provide aspiration using a vacuum. According to the applicant, the Lightning tubing performs clot detection using a proprietary algorithm. According to the applicant, once this ''smart technology'' detects free-flowing blood, it indicates patent flow to the physician and begins intermittent aspiration resulting in less blood loss during the procedure.

The applicant submitted a request for a unique ICD–10–PCS code to identify the technology and was granted

Agha, Michel Delforge, Fabio Petrocca, Payal Patel, Liping Huang, Timothy B. Campbell, Kristen Hege, Jesús F. San-Miguel, Idecabtagene vicleucel (ide-cel, bb2121), a BCMA-directed CAR T cell therapy, in relapsed and refractory multiple myeloma: Updated KarMMa results. ASCO 2021 Conference Proceedings, 2021: 8016; Gandhi, U.H., et al., Outcomes of patients with multiple myeloma refractory to CD38-targeted monoclonal antibody therapy. Leukemia, 2019. 33(9): 2266–2275.

[270] Heit, John A. ''Epidemiology of venous thromboembolism.'' *Nature reviews. Cardiology* vol. 12,8 (2015): 464–74. doi:10.1038/nrcardio.2015.83.

[271] Thomas L. Ortel, Ignacio Neumann, Walter Ageno, Rebecca Beyth, Nathan P. Clark, Adam Cuker, Barbara A. Hutten, Michael R. Jaff, Veena Manja, Sam Schulman, Caitlin Thurston, Suresh Vedantham, Peter Verhamme, Daniel M. Witt, Ivan D. Florez, Ariel Izcovich, Robby Nieuwlaat, Stephanie Ross, Holger J. Schünemann, Wojtek Wiercioch, Yuan Zhang, Yuqing Zhang; American Society of Hematology 2020 guidelines for management of venous thromboembolism: Treatment of deep vein thrombosis and pulmonary embolism. *Blood Adv* 2020; 4 (19): 4693–4738. doi: *https://doi.org/10.1182/bloodadvances.2020001830.*

[272] Karthikesalingam A, Young EL, Hinchliffe RJ, Loftus IM, Thompson MM, Holt PJ. A systematic review of percutaneous mechanical thrombectomy in the treatment of deep venous thrombosis. *Eur J Vasc Endovasc Surg.* 2011 Apr;41(4):554–65. doi: 10.1016/j.ejvs.2011.01.010. Epub 2011 Feb 1. PMID: 21288745.

[273] Brown KN, Devarapally SR, Lee L, et al. Catheter Directed Thrombolysis Of Pulmonary Embolism. [Updated 2020 Apr 10]. In: StatPearls [internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan. *https://www.ncbi.nlm.nih.gov/books/NBK536918/.*

[274] Karthikesalingam A, Young EL, Hinchliffe RJ, Loftus IM, Thompson MM, Holt PJ. A systematic review of percutaneous mechanical thrombectomy in the treatment of deep venous thrombosis. *Eur J Vasc Endovasc Surg.* 2011 Apr;41(4):554–65. doi: 10.1016/j.ejvs.2011.01.010. Epub 2011 Feb 1. PMID: 21288745.

[275] Haude, M. Mechanical thrombectomy catheter systems. *Interventional Cardiology* 2007;2(1):58–60.

approval for the following procedure codes effective October 1, 2021:

BILLING CODE 4120–01–P

ICD-10-PCS Code	Code Descriptor
X2CP3T7	Extirpation of matter from abdominal aorta using computer-aided mechanical aspiration, percutaneous approach, new technology group 7
X2CQ3T7	Extirpation of matter from right upper extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7
X2CR3T7	Extirpation of matter from left upper extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7
X2CS3T7	Extirpation of matter from right lower extremity artery using computer-aided mechanical aspiration, percutaneous approach, new technology group 7
X2CT3T7	Extirpation of matter from left lower extremity artery using computer-aided mechanical aspiration, percutaneous approach, new technology group 7
X2CU3T7	Extirpation of matter from right lower extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7
X2CV3T7	Extirpation of matter from left lower extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7
X2CY3T7	Extirpation of matter from great vessel using computer-aided mechanical aspiration, percutaneous approach, new technology group 7

INDIGO® with Lightning is a system with multiple components which have been reviewed by FDA both separately and as part of an overall system which includes catheters, tubing, and a vacuum pump. For the catheter portion of the system, INDIGO® aspiration catheter 12 (12 French) and separator 12 received FDA 510(k) clearance on May 28, 2020 for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems under FDA submission number K192981. The applicant stated that they submitted an application for FDA 510(k) clearance for that same technology (with a predicate which received clearance mentioned previously under submission number K192981) for indication of pulmonary embolism under FDA submission number K202821 for which clearance was completed on November 18, 2020. The INDIGO® aspiration catheter 12 and separator 12 received FDA 510(k) clearance for the peripheral arterial and venous system on the basis of similarity to an earlier version of the same catheter and separator, which itself received FDA 510(k) clearance on May 26, 2015 under FDA 510(k) number K142870 as part of the Penumbra Embolectomy System for the same indication. We note that the overall system received a second 510(k) clearance on December 20, 2019 under FDA 510(k) number K192833 for the added indication of PE.

With respect to the newness criterion for the tubing, the Lightning tubing received FDA 510(k) authorization for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems on March 13, 2020 under FDA 510(k) number K193244. The same tubing received

FDA 510(k) authorization for pulmonary embolism on April 22, 2020 under FDA 510(k) number K200771, which was granted based on substantial similarity to the same manufacturer's device. The predicate device for the peripheral arterial and venous system was an earlier version of the tubing without Lighting which itself received FDA 510(k) authorization on May 3, 2018 under FDA 510(k) number K180939.

With respect to the newness criterion for the vacuum pump, the Penumbra Engine Pump and Canister received FDA 510(k) clearance for use in the peripheral arterial and venous systems (PAVS) on March 8, 2018 under FDA 510(k) number K180105. The following table summarizes the FDA approval information listed in this section.

INDIGO® System	Indication	Reference Number	Date of Clearance
INDIGO® - Penumbra Embolectomy Aspiration System	PAVS	K142870	May 26, 2015
INDIGO® - Advanced 110 Aspiration Tubing	PAVS	K180939	May 3, 2018
INDIGO® - INDIGO Aspiration System	PE	K192833	December 20, 2019
INDIGO® - Penumbra ENGINE Pump and Canister	PAVS	K180105	March 8, 2018
INDIGO® - LIGHTNING Aspiration Tubing	PAVS	K193244	March 13, 2020
INDIGO® - LIGHTNING Aspiration Tubing	PE	K200771	April 22, 2020
INDIGO® – Aspiration Catheter 12 and Separator 12	PAVS	K192981	May 28, 2020
INDIGO® – Aspiration Catheter 12 and Separator 12	PE	K202821	November 18, 2020

BILLING CODE 4120–01–C

The applicant has applied for new technology add-on payments for INDIGO® with Lightning when used for the treatment of venous thromboembolism, arterial thromboembolism, and pulmonary thromboembolism.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that INDIGO® with Lightning does not use the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome. The applicant described differences between INDIGO® with Lightning and existing technologies based on the use of a mechanical pump to generate a vacuum for aspiration and the Lightning tubing, which the applicant stated limits blood loss and indicates clot versus patent flow. For pulmonary embolism and the peripheral system, the applicant identified Inari Flowtriever as an existing technology and noted that any aspiration provided using this system is provided via syringe as opposed to a vacuum pump. For the peripheral system, the applicant also identified Inari Flowtriever as using the same syringe method of aspiration. The applicant also identified two additional aspiration thrombectomy catheters, Angiojet® and Angiovac®, used in the peripheral system and suggested that Angiojet® also uses a syringe for aspiration and that Angiovac® utilizes an extracorporeal bypass circuit that is created outside the body consisting of an outflow line, a centrifugal pump, a filter and an inflow line.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that services provided using this device would be captured under MS–DRGs 163–165 and 270–272. MS–DRGs 163–165 address major chest procedures and MS–DRGs 270–272 address other major cardiovascular procedures.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant did not address this criterion directly in the application, but stated that the new use of the INDIGO® System with Lighting is for the most recent FDA indication (April 2020) in PE. The applicant further stated that PE is not the same disease as arterial and venous thromboembolism; the patient populations may overlap, but are not identical.

We noted the following concerns in the proposed rule (86 FR 25262 through 25263) regarding whether the technology meets the substantial similarity criteria and whether it should be considered new. While the applicant discussed the differences between INDIGO® with Lighting and products made by other manufacturers, the applicant did not provide enough information regarding how INDIGO® with Lightning differs in its components from the existing aspiration thrombectomy catheters on the market to determine whether the technology uses a unique mechanism of action. We questioned whether the mechanism of action of the pump is different than that of the existing aspiration thrombectomy systems that also use a pump rather than a syringe, and how the mechanism of action of the separator, which is part of the catheter portion of the device, is different from that of existing thrombectomy systems that deploy a

device through the lumen of the catheter to break up the thrombus. We also noted that it was unclear what mechanism of action is used within the ''smart technology'' and how it may differ from other products which are intended to similarly reduce blood loss during the procedure. It was unclear if the ''smart technology'' resides within the pump, which was cleared by FDA 510(k) on March 8, 2018, or within the tubing, which was most recently cleared by FDA 510(k) on April 22, 2020. We noted that while the applicant did not directly address the third criterion within the application, based on the clinical uses of the device described in the application, we believed the INDIGO® with Lightning is intended for a patient population that is similar to the patient population treated by existing thrombectomy devices, including patients who receive percutaneous interventions for PE and peripheral arterial thromboembolism.

We noted that the predicate device for the vacuum pump, the Penumbra Engine Pump and Canister, received FDA 510(k) clearance for use in the peripheral arterial and venous systems on March 8, 2018 under FDA 510(k) number K180105 and therefore appears to no longer be considered new. We further noted that the catheter and tubing, as described in the 510(k) applications, appear to only have minor differences from their predicate devices such as length of tubing and shelf life, as opposed to elements that would affect the mechanism of action. If we determine that the catheter and tubing are substantially similar to the predicate devices cleared under FDA 510(k) numbers K142870 (May 26, 2015) and K180939 (May 3, 2018), respectively, the newness date of the INDIGO® with Lightning would correspond to the dates listed and therefore may no longer be considered new. We also noted that it is unclear whether the components of the system may be substantially similar to the overall system and whether the applicable newness date for each indication would therefore be the date of the overall system clearance for each indication, specifically May 26, 2015 for peripheral arterial and venous systems and December 20, 2019 for pulmonary embolism.

We invited public comment on whether INDIGO® with Lightning is substantially similar to other technologies and whether INDIGO® with Lightning meets the newness criterion.

Comment: Several commenters asserted that INDIGO® with Lightning was substantially similar to other technologies and did not meet the qualifications for newness. These commenters suggested that the mechanism of action for INDIGO® with Lightning is identical to both previous versions of the same device (INDIGO® without Lightning) and other similar devices on the market. Specifically, a commenter identified the following examples of vacuum-based mechanical thrombectomy systems: Angiodynamics AngioVac System, the Philips QuickClear Mechanical Thrombectomy System, the Walk Vascular JETi Peripheral Thrombectomy System, and the Inari FlowTriever System. This commenter asserted that while INDIGO® with Lightning may be unique in using a pump to create a vacuum, other devices create a vacuum and the method of creating the vacuum is not relevant and does not represent a new mechanism of action. On the subject of the automated intermittent aspiration, some commenters noted that the same action can be completed using manual methods on the versions of INDIGO® without Lightning, such as by manually compressing the tubing to halt and restart suction, so that the automation does not represent a unique mechanism of action.

Response: We thank the commenters for their input on the mechanism of action of INDIGO® with Lightning and have taken these comments into consideration in our evaluation of the newness criterion, which is discussed later in this section.

Comment: The applicant submitted a letter stating that INDIGO® with Lightning meets the newness criterion. The applicant provided clarification regarding the INDIGO® with Lightning device and stated that the system is composed of two components: The engine that generates the vacuum (and can be used for multiple patients) which is a capital expense, and the Lightning device, tubing, catheter, and valve which are supplied together as a set and are single-use. The applicant stated that the Lightning device is the element of the system which is the subject of this application for new technology. The applicant also responded to our concern regarding when the device was cleared by the FDA, because we noted different dates of clearance for the pump and the tubing. The applicant asserted that because the Lightning device was an element of the tubing, it was cleared by the FDA for different indications on March 13, 2020 (K193244) and April 22, 2020 (K200771). The applicant noted the INDIGO® device that was cleared by the FDA on May 26, 2015, was not relevant to the new technology application because it did not include the Lightning device.

In response to our question whether the ''smart technology'' resided in the pump or within the tubing, the applicant stated that the ''smart technology'' is contained in a standalone Lightning device, which is used once per patient and placed on top of the engine. The standalone Lightning device contains a computer, sensors, and a valve. The applicant asserted that the INDIGO® with Lightning represented a unique mechanism of action that involves an integrated, computer-run, proprietary, smart algorithm which allows for the removal of a blood clot while limiting blood loss. Per the applicant, the device itself controls the opening and closing of the valve which is distinct from manual operation. The applicant highlighted a number of competitor products and suggested that none of them have a systemic method to differentiate blood from a clot.

In response to our concerns regarding how the mechanism of action of the separator differs from other existing thrombectomy systems, the applicant stated that the separator is not distinct from other technologies but was not integral to the consideration of newness for the device.

One additional commenter noted support for INDIGO® with Lightning meeting the requirements for a novel mechanism of action, stating that no other competitive system uses a vacuum pump with automatic flow limitation.

Response: We appreciate the commenter's input. We also thank the applicant for the additional information and for their comment regarding the newness criterion, including the clarification that the Lightning technology is the subject of this application. We agree with the applicant and commenter that this technology represents a new mechanism of action due to the way in which sensors and smart technology control the opening and closing of the valve allowing automated intermittent aspiration, as distinct from individual users' ability to manually compress the tubing, as described by a commenter. We agree that based on the clarification on the nature of the Lightning technology and how it integrates into the overall INDIGO® system, that the appropriate FDA clearances to consider are those for the Lightning technology for the indications of PAVS and PE, March 13, 2020 and April 22, 2020 respectively.

After consideration of the public comments we received and information submitted by the applicant as part of its FY 2022 new technology add-on payment application for INDIGO® with Lightning, we believe that INDIGO®

with Lightning has a unique mechanism of action in the treatment of patients for pulmonary embolism, deep vein thrombosis and peripheral arterial thromboembolism. Therefore, we believe that INDIGO® with Lightning is not substantially similar to existing treatment options and meets the newness criterion with the newness period beginning on March 13, 2020 for PAVS and April 22, 2020 for PE, the date on which the technology was cleared by FDA for each indication.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR claims data file with the FY 2019 Final Rule with Correction Notice IPPS Impact File to identify potential cases representing patients who may be eligible for treatment using the INDIGO® System. The applicant identified claims with any one of the following ICD–10–PCS codes for percutaneous mechanical thrombectomy:

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Pulmonary Embolism	
02CP3ZZ	Extirpation of matter from pulmonary trunk, percutaneous approach
02CQ3ZZ	Extirpation of matter from right pulmonary artery, percutaneous approach
02CR3ZZ	Extirpation of matter from left pulmonary artery, percutaneous approach
02CS3ZZ	Extirpation of matter from right pulmonary vein, percutaneous approach
02CT3ZZ	Extirpation of matter from left pulmonary vein, percutaneous approach
Deep Vein Thrombosis/Vascular	
04CC3Z6	Extirpation of matter from right common iliac artery, bifurcation, percutaneous approach
04CC3ZZ	Extirpation of matter from right common iliac artery, percutaneous approach
04CD3Z6	Extirpation of matter from left common iliac artery, bifurcation, percutaneous approach
04CD3ZZ	Extirpation of matter from left common iliac artery, percutaneous approach
04CE3Z6	Extirpation of matter from right internal iliac artery, bifurcation, percutaneous approach
04CE3ZZ	Extirpation of matter from right internal iliac artery, percutaneous approach
04CF3Z6	Extirpation of matter from left internal iliac artery, bifurcation, percutaneous approach
04CF3ZZ	Extirpation of matter from left internal iliac artery, percutaneous approach
04CH3Z6	Extirpation of matter from right external iliac artery, bifurcation, percutaneous approach
04CH3ZZ	Extirpation of matter from right external iliac artery, percutaneous approach
04CJ3Z6	Extirpation of matter from left external iliac artery, bifurcation, percutaneous approach
04CJ3ZZ	Extirpation of matter from left external iliac artery, percutaneous approach
04CK3Z6	Extirpation of matter from right femoral artery, bifurcation, percutaneous approach
04CK3ZZ	Extirpation of matter from right femoral artery, percutaneous approach
04CL3Z6	Extirpation of matter from left femoral artery, bifurcation, percutaneous approach
04CL3ZZ	Extirpation of matter from left femoral artery, percutaneous approach
04CM3Z6	Extirpation of matter from right popliteal artery, bifurcation, percutaneous approach
04CM3ZZ	Extirpation of matter from right popliteal artery, percutaneous approach

04CN3Z6	Extirpation of matter from left popliteal artery, bifurcation, percutaneous approach
04CN3ZZ	Extirpation of matter from left popliteal artery, percutaneous approach
04CP3Z6	Extirpation of matter from right anterior tibial artery, bifurcation, percutaneous approach
04CP3ZZ	Extirpation of matter from right anterior tibial artery, percutaneous approach
04CQ3Z6	Extirpation of matter from left anterior tibial artery, bifurcation, percutaneous approach
04CQ3ZZ	Extirpation of matter from left anterior tibial artery, percutaneous approach
04CR3Z6	Extirpation of matter from right posterior tibial artery, bifurcation, percutaneous approach
04CR3ZZ	Extirpation of matter from right posterior tibial artery, percutaneous approach
04CS3Z6	Extirpation of matter from left posterior tibial artery, bifurcation, percutaneous approach
04CS3ZZ	Extirpation of matter from left posterior tibial artery, percutaneous approach
04CT3Z6	Extirpation of matter from right peroneal artery, bifurcation, percutaneous approach
04CT3ZZ	Extirpation of matter from right peroneal artery, percutaneous approach
04CU3Z6	Extirpation of matter from left peroneal artery, bifurcation, percutaneous approach
04CU3ZZ	Extirpation of matter from left peroneal artery, percutaneous approach
06CC3ZZ	Extirpation of matter from right common iliac vein, percutaneous approach
06CD3ZZ	Extirpation of matter from left common iliac vein, percutaneous approach
06CF3ZZ	Extirpation of matter from right external iliac vein, percutaneous approach
06CG3ZZ	Extirpation of matter from left external iliac vein, percutaneous approach
06CM3ZZ	Extirpation of matter from right femoral vein, percutaneous approach
06CN3ZZ	Extirpation of matter from left femoral vein, percutaneous approach

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In its analysis, the applicant identified a primary cohort to assess whether this therapy met the cost criterion. The previously listed ICD–10–PCS procedure codes were used to identify claims involving percutaneous procedures. The claim search conducted by the applicant resulted in 15,580 claims mapping to six MS–DRGs: 270 (Other Major Cardiovascular Procedures with MCC), 271 (Other Major Cardiovascular Procedures with CC), 272 (Other Major Cardiovascular Procedures without CC/MCC), 163 (Major Chest Procedures with MCC), 164 (Major Chest Procedures with CC), and 165 (Major Chest Procedures without CC/MCC).

The applicant determined an average unstandardized case weighted charge per case of $126,211.

The applicant did not remove charges for prior technology. The applicant stated that no prior technology is being replaced. The applicant then standardized the charges using the FY 2019 Final Rule with Correction Notice Impact File. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the new technology, the applicant used what it stated was the national average CCR for the Supplies and Equipment cost center of 0.299 from the FY 2021 IPPS final rule. However, we noted that the actual value for this cost center for FY 2021 was 0.297. The applicant calculated a final inflated average case-weighted standardized charge per case of $180,036, which exceeded the

average case-weighted threshold amount of $126,211 by $53,825. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

We invited public comment on whether INDIGO® with Lightning meets the cost criterion.

Comment: We received a public comment from the applicant on whether the INDIGO® Aspiration System with Lightning Aspiration Tubing meets the cost criterion. The applicant noted that CMS stated in the proposed rule that they did not remove charges for prior technology (86 FR 25265). The applicant clarified that in their cost analysis they did remove charges of $11,505 per case for existing technology based on a calculation of using the current price of $3,440 and dividing it by the FY 2019 national cost-to-charge ratio for supplies and equipment of 0.299 to determine charges for the existing technology. The applicant stated that they applied the national cost-to-charge ratio for supplies and equipment of 0.299 to the known cost of existing equipment because the claims data are from the FY 2019 MedPAR claims data file. The applicant believes this would have been the charges applied for the existing technology in 2019 and was therefore the most appropriate cost-to-charge ratio to use. The applicant further commented that they think it is important to note that in performing the cost calculation, they used the national average cost-to-charge ratio for the Supplies and Equipment cost center of 0.297 from the FY 2021 IPPS final rule. The applicant further commented that their application notes that they then added the weighted average charge for the new technology of $22,596 to the charges. The weighted average charge for the new technology (comprised of the catheter(s) and Lightning Device) is $6,711, which was divided by 0.297 to arrive at a charge of $22,596. The applicant noted that the appropriate charges for the existing technology were removed prior to standardizing the charges and the charges for the new technology were applied using the appropriate cost-to-charge ratio. The applicant stated that since the final inflated average case-weighted standardized charge per case of $180,036 exceeds the average case-weighted threshold amount of $126,211 that the INDIGO® System meets the cost criterion.

Response: We thank the applicant for their comment regarding the INDIGO® system meeting the cost criterion. Based on the information submitted by the applicant as part of its FY 2022 new technology add-on payment application, as discussed in the proposed rule (86 FR 25261 through 25266) and previously summarized and the comment received, we agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount as previously stated. Therefore, the INDIGO® System meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the INDIGO® with Lightning represents a substantial clinical improvement over existing technologies because it results in lower rates of aspirated blood loss during the procedure, low major bleeding event rate, reduces blood loss, reduces ICU stays, and reduces procedure time. The applicant also suggested that the technology allows for revascularization without thrombolytics and no recurrence of pulmonary embolism after 30 days.

To support its application, the applicant submitted a reference to the EXTRACT–PE prospective, single-arm study across 22 sites comparing the use of INDIGO® without Lightning to systemic thrombolysis in 119 patients with PE who had not been previously treated with anti-thrombolytics or an adjunctive device within 48 hours. The applicant stated that this study was completed under FDA Investigational Device Exception (IDE) G170064. The applicant claimed that the EXTRACT–PE study showed the INDIGO® without Lightning led to a significant mean reduction of 0.43 in right ventricle/left ventricle (RV/LV) ratio (a measure associated with poor clinical outcomes when greater than 1) that corresponded to a 27.3 percent reduction at 48 hours after intervention. They also cited a low major adverse event composite rate of 1.7 percent within 48 hours, device usage of only 37 minutes and median ICU length of stay of 1 day. According to the applicant, rates of cardiac injury, pulmonary vascular injury, clinical deterioration, major bleeding, and device-related death at 48 hours were 0%, 1.7%, 1.7%, 1.7%, and 0.8%, respectively.

The applicant cited a poster of an unpublished retrospective case review study by Hastings [276] of 18 patients with DVT treated with INDIGO® followed by anticoagulation. Primary technical success (defined as restoration of blood flow with minimal residual thrombus (<10%) without the need for a second session of treatment) was achieved in 15 patients. Three patients required adjunctive methods for successful clearance of thrombus, undergoing two sessions of treatment. Two patients had recurrence of DVT following single-session treatment, both of whom were asymptomatic at time of diagnosis.

The applicant cited the PRISM study,[277] a single-arm, multicenter, retrospective analysis of 79 patients with arterial occlusion from 2018, to provide evidence that use of INDIGO® with Lightning has a low major bleeding event rate, can result in revascularization without thrombolytics, and causes no clinically significant distal embolization. The applicant also stated that the interim results of the INDIAN study, a prospective trial using INDIGO® without Lightning to treat patients with ALI showed no device-related adverse events or major bleeding complications.[278]

The applicant asserted that an unpublished laboratory bench test using water found that the 20.3 mL/sec average flow rate of catheter with Lightning generates 18-fold reduction in blood loss when compared to the use of the same catheter and Penumbra engine pump without the Lightning technology. The applicant asserted that a bench test showed that the Penumbra aspiration pump demonstrates continuous pressure, as evidenced by a sustained −29 inHg (inches of Mercury) through 60 seconds versus a 60-ml syringe which starts at −27 Hg and drops to 0 in Hg within 18 seconds.

The applicant also asserted that an abstract of a single-center retrospective case-control trial of 38 patients by Muck, P., et al. comparing two versions of INDIGO® catheters (12F and 8F) showed that median blood loss was 250mL in the larger Lightning 12F arm (n=9, larger catheter) and 375mL in the 8F arm without Lightning (n=27, smaller catheter). Technical success (defined as greater than 70 percent thrombus reduction) was achieved in 77 percent of patients in the Lightning 12F arm compared to 18.5 percent in the 8F arm without Lightning. The applicant also asserted that this study showed that

[276] Hastings, L.H., Perkowski, P.E. Single Session Percutaneous Mechanical Aspiration Thrombectomy for Symptomatic Proximal Deep Vein Thrombosis. Poster.

[277] Saxon, R.R., Benenati, J.F., Teigen, C., Adams, G.K., Sewall, L.E., and Trialists, P. (2018). Utility of a power aspiration-based extraction technique as an initial and secondary approach in the treatment of peripheral arterial thromboembolism: Results of the multicenter prism trial. *J Vasc Interv Radiol.* 29(1): p. 92–100.

[278] Donato, et al. Acute Lower Limb Malperfusion—(INDIAN) Registry: Protocol (as presented at VEITHsymposium 2019).

none (0/9) of the patients in the INDIGO® with Lightning group required post-procedure transfusion, whereas 18.5 percent (5/27) of the INDIGO® without Lightning group required post-procedure transfusion.

In the proposed rule (86 FR 25265 through 25266), we noted the following concerns in regard to the substantial improvement criterion. Specifically, in its application, the applicant did not explicitly state what the comparator was for each of its claims in support of substantial clinical improvement; for example, whether INDIGO® is being compared to systemic thrombolysis, percutaneous catheter directed thrombolysis, or other aspiration thrombectomy catheters. We stated that comparing INDIGO® to a medical treatment modality may not be appropriate since percutaneous interventions for PE and DVT have different clinical indications, risks, and benefits compared to medical or surgical interventions.

We also noted that the applicant relies mostly on studies of INDIGO® without Lightning to substantiate its claims regarding INDIGO® with Lightning. Of all the studies provided by the applicant, only one small, unpublished study of DVT patients by Muck, P., et al. includes patients treated with INDIGO® with Lightning (which has the intelligent aspiration) versus earlier versions of the applicant's device. We stated that the applicant did not demonstrate superior outcomes using INDIGO® with Lightning compared to INDIGO® without Lightning.

We noted that outcomes for INDIGO® for the rates of pulmonary vascular injury at 48 hours, clinical deterioration, major bleeding and device-related deaths were stated by the applicant as low compared to systemic thrombolysis, but were not compared to outcomes for existing aspiration thrombectomy devices which may be a more appropriate comparator. We further noted that in the poster study, all patients were maintained on anticoagulation following thrombectomy with INDIGO®, so it is difficult to assess the DVT recurrence rate (using INDIGO® alone) to support the claim that INDIGO® can be used with patients with high risk of bleeding.

We also noted that suction generated through a vacuum may not be superior to other mechanisms of generating negative pressure used in other existing aspiration catheters. A study comparing suction forces and vacuum pressure of Penumbra pump to a 60-mL syringe and pumps manufactured by several other manufacturers showed that all catheters transmit similar vacuum pressure regardless of pump or 60-mL syringe.[279]

Finally, we questioned whether there is enough evidence to support that ''intelligent aspiration'' associated with INDIGO with Lightning provides a substantial clinical improvement over existing aspiration catheters from INDIGO® and existing devices where the aspiration is controlled manually. No direct comparison of blood loss between INDIGO® with Lightning catheter and existing aspiration thrombectomy devices from other manufacturers was provided, specifically catheters that reduce blood loss by returning the aspirated blood back to the patient. The unpublished bench test included with the application may have demonstrated a reduction in average volume of water aspirated using the INDIGO® Catheter with Lightning fully functional compared to the INDIGO® catheter with Lightning deactivated (valve pin fixed to the open position). However, this study was not designed to compare blood loss during a thrombectomy procedure between aspiration controlled by a human versus by the Lightning ''intelligent aspiration.''

We invited public comment on whether INDIGO® with Lightning meets the substantial clinical improvement criterion.

Comment: Several commenters stated that they did not believe that INDIGO® with Lightning met the requirements for substantial clinical improvement. Some comments stated in general that their clinical experience with other competing mechanical thrombectomy products was superior. Other commenters noted that there was no published data to suggest that INDIGO® with Lightning offered improved outcomes over competitive products. Some commenters discussed personal experience with INDIGO® with Lightning and discussed concerns including a tendency for the catheter to be clogged with thrombus requiring removal and cleaning, which results in additional blood loss. A commenter noted their experience with many other products and asserted that blood loss was much higher using INDIGO® with Lightning. This same commenter stated that there was some difficulty in achieving good clearance of thrombus using INDIGO® with Lightning. A commenter reviewed the clinical evidence submitted by the applicant and asserted that no patients were treated with INDIGO® with Lightning in the studies demonstrating arterial or venous thromboembolism clinical evidence because the studies took place prior to the availability of the technology. The commenter also noted that the unpublished laboratory bench test which was submitted by the applicant used water as opposed to blood to demonstrate effectiveness. This same commenter asserted that only a single study of INDIGO® with Lightning was used to demonstrate clinical evidence and that it was an unpublished abstract which included nine patients with DVT. The same commenter then summarized a study of a competitive product, the Inari ClotTriever, stating that a multi-center study of DVT patients showed a median blood loss of 50ml.[280] The same commenter summarized a multi-center study of pulmonary embolism patients treated with another competitive product, the Inari FlowTriever, that showed a median blood loss of 250ml.[281] This commenter asserted that this evidence was both more robust due to the larger number of patients and demonstrated reduced blood loss when compared to evidence presented for INDIGO® with Lightning.

Response: We appreciate the commenters providing their personal experience with the device as well as their comments on the evidence that the applicant included provided and have taken these comments into consideration in our determination of substantial clinical improvement, which is discussed later in this section.

Comment: The applicant submitted a comment in response to our concerns regarding whether INDIGO® with Lightning meets the substantial clinical improvement criterion.

In response to the concern that the comparator for the submitted studies was unclear, the applicant stated that, in general, other aspiration thrombectomy systems are the appropriate comparators in the consideration of substantial clinical improvement for INDIGO® with Lightning. The applicant provided a table which indicated the comparators that were used in studies that were part of the application as well as one new study that was provided with the

[279] Froehler, M.T. (2017). Comparison of vacuum pressures and forces generated by different catheters and pumps for aspiration thrombectomy in acute ischemic stroke. Interventional neurology, 6(3–4), 199–206.

[280] Prospective data from first 250 DVT patients enrolled across 24 study site in the ClotTriever Outcomes Registry as presented at 2021 New Cardiovascular Horizons Annual Conference.

[281] Prospective data from first 230 PE patients enrolled in the FlowTriever All-Comer Registry for Patient Safety and Hemodynamics as presented at the 2020 American Heart Association and the 2020 Transcatheter Cardiovascular Therapeutics Conference.

comment submission, summarized in the table below.

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Table XX

Substantial Clinical Improvement Claim	**Comparator**
Low major bleeding event rate	INDIGO® (without Lightning) is associated with lower major bleeding and other adverse events when compared to the AngioJet Peripheral Thrombectomy System. [282] The applicant further asserted that the addition of the Lightning device would further improve the reduction and widen the gap between INDIGO® with Lightning and other aspiration thrombectomy systems.
Reduction in blood loss	Using INDIGO® without Lightning as a proxy for other aspiration thrombectomy systems without Lightning, INDIGO® with Lightning demonstrated reduction in blood loss compared to INDIGO® without Lightning in a bench test and a single center retrospective case control study, which was presented in May of 2021 and for which the poster was included in the submission. [283]
Revascularization without thrombolytics	The INDIGO® system (using both the Penumbra engine and the Lightning device) results in greater revascularization without thrombolytics compared to other aspiration thrombectomy systems.[284] [285]

Technical success (defined in part as thrombus reduction in a single session)	INDIGO® with Lightning demonstrated improvement over aspiration thrombectomy systems without the Penumbra engine or Lightning device.[286]
Freedom from recurrence	INDIGO® with Lightning was compared to catheter-directed mechanical thrombectomy, other aspiration thrombectomy systems, and fibrinolysis.[287] The applicant further noted that in the EXTRACT-PE study, that 0.0% of patients presented with symptomatic PE recurrence within 30 days. The applicant compared that result to 1.9% for catheter-directed thrombolysis and 2.5% for systemic thrombolysis, and 0.2% for systemic tenecteplase.
Shorter procedure time	The Penumbra engine has been shown to reduce procedure times as compared to catheter-directed, low-dose fibrinolysis and catheter-directed mechanical thrombectomy.

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With regard to our concern that the application relied mostly on studies of INDIGO® without Lightning, the applicant described a recent presentation in May 2021 [288] which compared the use of INDIGO® without Lightning to INDIGO® with Lightning. The applicant stated that the use of the intelligent aspiration associated with the Lightning device was associated with higher rates of technical success, less blood loss, and no need for blood transfusion when compared to continuous aspiration. With respect to technical success, the new submitted study reported that thrombus reduction of >70% or better was significantly higher in the Lightning group. The applicant further noted that 80% of patients in the Lightning group achieved thrombus reduction of >70% compared to only 20% of patients in the control group. With respect to blood loss, the investigators found a significant reduction in blood loss when using the Lightning Device (250mL versus 275mL blood loss, p=0.0044). They also noted that none of the patients in the Lightning group required a post-procedure transfusion whereas 16.7% of the patients without Lightning did.

With regard to our concern that it was difficult to assess the DVT recurrence rate (using the INDIGO® System alone) to support the claim that the INDIGO® System can be used with patients with high risk of bleeding because in the poster study submitted with the application, all patients were

[282] EXTRACT–PE: A Prospective, Multicenter Trial to Evaluate the Safety and Efficacy of the Indigo® Aspiration System in Acute Pulmonary Embolism—as presented at VIVA 2019; Saxon, R.R., Benenati, J.F., Teigen, C., Adams, G.K., Sewall, L.E., and Trialists, P. (2018). Utility of a power aspiration-based extraction technique as an initial and secondary approach in the treatment of peripheral arterial thromboembolism: Results of the multicenter prism trial. J Vasc Interv Radiol. 29(1): p. 92–100.

[283] EXTRACT–PE: A Prospective, Multicenter Trial to Evaluate the Safety and Efficacy of the Indigo® Aspiration System in Acute Pulmonary Embolism—as presented at VIVA 2019; Saxon, R.R., Benenati, J.F., Teigen, C., Adams, G.K., Sewall, L.E., and Trialists, P. (2018). Utility of a power aspiration-based extraction technique as an initial and secondary approach in the treatment of peripheral arterial thromboembolism: Results of the multicenter prism trial. J Vasc Interv Radiol. 29(1): p. 92–100.

[284] EXTRACT–PE: A Prospective, Multicenter Trial to Evaluate the Safety and Efficacy of the Indigo® Aspiration System in Acute Pulmonary Embolism—as presented at VIVA 2019; Saxon, R.R., Benenati, J.F., Teigen, C., Adams, G.K., Sewall, L.E., and Trialists, P. (2018). Utility of a power aspiration-based extraction technique as an initial and secondary approach in the treatment of peripheral arterial thromboembolism: Results of the multicenter prism trial. J Vasc Interv Radiol. 29(1): p. 92–100.

[285] Muck, P., et al. Aspiration Thrombectomy with and without Intelligent Aspiration for Lower Extremity Acute Deep Vein Thrombosis, Poster, presented at International Symposium on Endovascular Therapy (May 9–11, 2021).

[286] EXTRACT–PE: A Prospective, Multicenter Trial to Evaluate the Safety and Efficacy of the Indigo® Aspiration System in Acute Pulmonary Embolism—as presented at VIVA 2019; Muck, P., et al. SCVS Abstract; Hastings, L.H., Perkowski, P.E, Single Session Percutaneous Mechanical Aspiration Thrombectomy for Symptomatic Proximal Deep Vein Thrombosis Poster.

[287] Meyer et al (Apr. 2014). Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism. N Engl J Med. 10;370(15):1402–11); Tu et al (May 2019). A Prospective, Single-Arm, Multicenter Trial of Catheter-Directed Mechanical Thrombectomy for Intermediate-Risk Acute Pulmonary Embolism: The FLARE Study. JACC Cardiovasc Interv. 13;12(9):859–869; EXTRACT–PE: A Prospective, Multicenter Trial to Evaluate the Safety and Efficacy of the Indigo® Aspiration System in Acute Pulmonary Embolism—as presented at VIVA 2019; Hastings, L.H., Perkowski, P.E, Single Session Percutaneous Mechanical Aspiration Thrombectomy for Symptomatic Proximal Deep Vein Thrombosis Poster.

[288] Muck, P., et al. Aspiration Thrombectomy with and without Intelligent Aspiration for Lower Extremity Acute Deep Vein Thrombosis, Poster, presented at International Symposium on Endovascular Therapy (May 9–11, 2021).

maintained on anticoagulation following thrombectomy with the INDIGO® System, the applicant asserted that anticoagulation for DVT is standard practice regardless of risk for bleeding. Thus, in order to isolate the outcomes associated with INDIGO®, the applicant stated it was necessary to maintain DVT patients on anticoagulation, as it is the standard of care.

With regard to our concern about whether suction generated through a vacuum (as in the case of the INDIGO® System) is superior to other mechanisms of generating negative pressure used in other existing aspiration catheters, the applicant noted that they do not believe the suction associated with the INDIGO® System, which is related to the Penumbra Engine, is relevant to the new technology add-on payment application because it is the Lightning device that is the component of import with respect to substantial clinical improvement, but noted their belief that the suction generated by the Penumbra engine is superior to other methods of generating a vacuum.

Several other commenters noted their support for INDIGO® with Lightning demonstrating substantial clinical improvement. Some of these commenters did not offer specific points of comparison but spoke to their personal clinical experience with the device. Other commenters pointed to the ability of INDIGO® with Lightning to reduce blood loss, increase the likelihood of completing treatment in a single session and reduce the required use of thrombolytics.

Response: We appreciate the comments and the additional data from the applicant received for INDIGO® with Lightning and have taken them into consideration in making our determination. We believe the applicant was able to address our concern regarding the continuation of anticoagulation for DVT. We also appreciate the clarification from the applicant regarding our concern that the Penumbra engine is not part of its application for new technology add-on payments, thereby resolving our concern with regard to the superiority of the vacuum suction. However, after review of all the data received to date, we continue to have concerns regarding the substantial clinical improvement criterion as noted in the FY 2022 IPPS/LTCH PPS proposed rule. Specifically, we remain concerned that the applicant primarily used data from studies that utilized INDIGO® without Lightning in their attempt to demonstrate superior outcomes using INDIGO® with Lightning which is the subject of this application. While the applicant provided an additional May 2021 presentation that compared INDIGO® with Lightning to INDIGO® without Lightning, we do not believe it is appropriate to consider INDIGO® without Lighting as a proxy for other existing mechanical thrombectomy devices as stated by the applicant. We note that multiple comments suggest that other mechanical thrombectomy devices may be superior to the comparator device of INDIGO® without Lightning, and the applicant did not provide data comparing INDIGO® with Lightning to any existing device (other than INDIGO® without Lightning) to demonstrate improved outcomes. For these reasons, we do not have sufficient evidence to support that INDIGO® with Lightning provides a substantial clinical improvement over existing aspiration catheters including INDIGO® and existing devices where the aspiration is controlled manually.

After consideration of all the information from the applicant, as well as the comments we received, we are unable to determine that INDIGO® with Lightning represents a substantial clinical improvement over existing technologies, and we are not approving new technology add-on payments for INDIGO® with Lightning for FY 2022.

i. Olumiant® (baricitinib)

Eli Lilly and Company submitted an application for new technology add-on payments for Olumiant® (baricitinib) for FY 2022. Olumiant® is a Janus kinase (JAK) 1 and 2 inhibitor used in combination with remdesivir as a treatment option for coronavirus disease 2019 (COVID–19), a respiratory disease caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2). Olumiant® has not yet received marketing approval from FDA to treat COVID–19, but has received an emergency use authorization (EUA) by the FDA. Olumiant® has been previously approved by FDA for the treatment of adult patients with moderately to severely active rheumatoid arthritis, who have had inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.[289]

The applicant stated that patients diagnosed with COVID–19 are at an elevated risk for excess morbidity and mortality due to the underlying SARS–CoV–2 infection and subsequent cytokine activation. The applicant stated that the cause of respiratory failure in COVID–19 is a hyperinflammatory state characterized by upregulation of multiple cytokines and that Olumiant® may be a viable treatment in patients with COVID–19 requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) because of its anti-inflammatory activity and ability to reverse dysregulated inflammatory markers in patients with COVID–19.[290] The applicant noted treatment with baricitinib 4 mg resulted in reduced plasma levels of the cytokine IL–6 in hospitalized patients with COVID–19, a finding that was replicated after being observed in patients with rheumatoid arthritis.[291] [292] [293] The applicant also claimed that Olumiant® potentially has anti-viral activity in inhibiting SARS–CoV–2 from entering and infecting lung cells due to its affinity for adaptor-associated kinase-1 (AAK1).[294] The applicant noted that there are ongoing studies to evaluate the impact of the antiviral host activity of Olumiant®.

With respect to the newness criterion, Olumiant® received Emergency Use Authorization (EUA) from FDA on November 19, 2020 for the emergency use of Olumiant®, indicated for use in combination with remdesivir for the treatment of suspected or laboratory confirmed COVID–19 in certain hospitalized patients requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). The applicant stated that it intends to submit a supplemental new drug application (sNDA) for Olumiant®.

[289] Olumiant (baricitinib) [package insert]. US Food and Drug Administration. Available at *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/207924s002lbl.pdf*. Revised July 8, 2020. Accessed October 8, 2020.

[290] McInnes IB, Byers NL, Higgs RE, et al. Comparison of baricitinib, upadacitinib, and tofacitinib mediated regulation of cytokine signaling in human leukocyte subpopulations. Arthritis Res Ther. 2019;21(1):183. *https://doi.org/10.1186/s13075-019-1964-1*.

[291] Bronte V, Ugel S, Tinazzi E, et al. Baricitinib restrains the immune dysregulation in severe COVID–19 patients [published online August 18, 2020]. J Clin Invest. *https://doi.org/10.1172/JCI141772*.

[292] Sims JT, Krishnan V, Chang CY, et al. Characterization of the cytokine storm reflects hyperinflammatory endothelial dysfunction in COVID–19 [published online September 10, 2020]. J Allergy Clin Immunol. *https://doi.org/10.1016/j.jaci.2020.08.031*.

[293] Stebbing J, Krishnan V, de Bono S, et al; Sacco Baricitinib Study Group. Mechanism of baricitinib supports artificial intelligence-predicted testing in COVID–19 patients. EMBO Mol Med. 2020;12(8):e12697. *https://doi.org/10.15252/emmm.202012697*.

[294] Richardson P, Griffin I, Tucker C, Smith D, Oechsle O, Phelan A, Rawling M, Savory E, Stebbing J. Baricitinib as potential treatment for 2019–nCoV acute respiratory disease. Lancet. 2020 Feb 15;395(10223):e30–e31. doi: 10.1016/S0140–6736(20)30304–4. Epub 2020 Feb 4. Erratum in: Lancet. 2020 Jun 20;395(10241):1906. PMID: 32032529; PMCID: PMC7137985.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we revised our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. We stated that new technologies that have not received FDA approval do not meet the newness criterion. In addition, we stated we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective. For these reasons, we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also finalized at 42 CFR 412.87(c) (subsequently redesignated as § 412.87(e)) that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances, licensures, and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to § 412.87(e)(2) to indicate that new technologies must receive FDA marketing authorization (for example, pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; approval of a New Drug Application (NDA); or Biologics License Application (BLA) licensure) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As noted in the FY 2021 IPPS/LTCH PPS final rule, this technical clarification did not change our longstanding policy for evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, and we continue to consider FDA marketing authorization as representing that a product has received FDA approval or clearance for purposes of eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

An EUA by the FDA allows a product to be used for emergency use, but under our longstanding policy, we believe it would not be considered an FDA marketing authorization for the purpose of new technology add-on payments, as a product that is available only through an EUA is not considered to have FDA approval or clearance. Therefore, under the current regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible for new technology add-on payments.

We also refer the reader to our comment solicitation in section II.F.7. of the preamble of the proposed rule regarding how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA. With respect to Olumiant®, we specifically requested comment on whether the newness period for this technology would begin on November 19, 2020, the date of its EUA, when the product became available on the market. We summarize comments related to this comment solicitation and provide our responses as well as our finalized policy in section XXX of this final rule.

In response to the COVID–19 public health emergency (PHE), we established the New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71155). We believe that as drugs and biological products become available and are authorized for emergency use or approved by FDA for the treatment of COVID–19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE. Therefore, effective for discharges occurring on or after November 2, 2020 and until the end of the PHE for COVID–19, we established the NCTAP to pay hospitals the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID–19.[295] Qualifying inpatient cases involving the use of Olumiant®, in combination with VEKLURY®, are currently eligible for NCTAP beginning November 19, 2020, the date Olumiant® received EUA, through the end of the PHE.

We stated in the proposed rule that we anticipated that there might be inpatient cases of COVID–19, beyond the end of the PHE, for which payment based on the assigned MS–DRG may not adequately reflect the additional cost of new COVID–19 treatments. In order to continue to mitigate potential financial disincentives for hospitals to provide new treatments, and to minimize any potential payment disruption immediately following the end of the PHE, we stated that we believe that the NCTAP should remain available for cases involving eligible treatments, including Olumiant®, in combination with VEKLURY®, for the remainder of the fiscal year in which the PHE ends (for example, until September 30, 2022). We refer the reader to our proposal in section II.F.8. of the preamble of the proposed rule to extend the NCTAP through the end of the fiscal year in which the PHE ends for certain products and discontinue the NCTAP for products approved for new technology add-on payments in FY 2022. We also refer the reader to section XXX of the preamble of this final rule, where we discuss our finalized policy to extend the NCTAP through the end of the fiscal year in which the PHE ends for all eligible products.

The applicant indicated that Olumiant® could be reported using the ICD–10–PCS codes 3E0DXGC (Introduction of other therapeutic substance into mouth and pharynx, external approach) or 3E0G7GC (Introduction of other therapeutic substance into upper GI, via natural or artificial opening) but stated that these codes do not uniquely identify the administration of Olumiant®. We noted that ICD–10–PCS codes XW0DXF5 (Introduction of other new technology therapeutic substance into mouth and pharynx, external approach, new technology group 5) and 3E0H7GC (Introduction of other therapeutic substance into lower G.I. via natural or artificial opening) could also be used to report use of Olumiant®. We noted that as of January 1, 2021, Olumiant® is

[295] Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 71142, 71155 (November 6, 2020). *https://www.govinfo.gov/content/pkg/FR-2020-11-06/pdf/2020-24332.pdf.*; For more information on NCTAP, refer to CMS' provider toolkit at *https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap.*

uniquely identified by ICD–10–PCS codes XW0DXM6 (Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6), XW0G7M6 (Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6), and XW0H7M6 (Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, Olumiant® does not use the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome, as there are no JAK inhibitor therapies that have received an EUA or an approval from FDA to treat COVID–19.

The applicant notes that currently there is one therapy approved by FDA to treat COVID–19 in hospital inpatients, remdesivir, and one therapy, besides Olumiant®, that has received EUA for the treatment of COVID–19, convalescent plasma.[296] The applicant claims that the mechanism of action for both of these treatments differs from Olumiant®, which works as a JAK inhibitor.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that there are no JAK inhibitor therapies that have received an EUA or an approval from FDA for the treatment of patients with COVID–19 and that Olumiant® could therefore not be assigned to the same MS–DRG as existing technologies.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, Olumiant® represents a potential new treatment option for adult and pediatric patients 2 years or older with suspected or laboratory-confirmed COVID–19 requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). The applicant also stated that COVID–19 is an entirely distinct disease from those caused by other coronaviruses including severe acute respiratory syndrome (SARS) and the Middle East respiratory syndrome coronavirus (MERS–CoV).

In summary, the applicant asserted that Olumiant® is not substantially similar to other available therapies because, as a JAK inhibitor, it has a unique mechanism of action; there are no other products assigned to the same MS–DRG; and it treats a different patient population and disease—COVID–19. However, we stated in the proposed rule that although there may not be any other JAK inhibitors for the treatment of COVID–19 assigned to the same MS–DRG as Olumiant®, Olumiant® may map to the same MS–DRG as other existing COVID–19 treatments. We also noted that Olumiant® involves the treatment of the same patient population and disease as other treatments for COVID–19, as Olumiant® is given to the same patients as remdesivir due to the EUA indication.

As discussed in section II.F.7 of the preamble of the proposed rule, we requested comment regarding how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA. We also specifically requested comment on whether the newness period for Olumiant® would begin on November 19, 2020, the date of its EUA, when the product became available on the market. We summarize comments related to this comment solicitation and provide our responses as well as our finalized policy in section XXX of this final rule.

As previously discussed, under the regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible for new technology add-on payments.

We invited public comment on whether Olumiant® meets the newness criterion.

Comment: In response to CMS' statement in the proposed rule that an EUA would not be considered FDA marketing authorization for the purpose of new technology add-on payments, as a product that is available only through an EUA is not considered to have FDA approval or clearance, and therefore a product available only through an EUA would not be eligible for new technology add-on payments, the applicant submitted a comment. The applicant stated their belief that market authorization, not approval, is the criterion for new technology add-on payment eligibility and that an EUA is a formal FDA authorization to market. Further, the applicant stated that if an EUA was sufficient for CMS to authorize payment enhancements on COVID treatments under NCTAP, the same EUA should suffice for the new technology add-on payment's marketing authorization requirement and that in the case of COVID therapies, CMS should harmonize its payment policies to ensure consistency and prevent lapses in reimbursement that could lead to access barriers for patients. The applicant requested that CMS reconsider its stated position and acknowledge that an active EUA issued by the FDA for a COVID–19 treatment prior to July 1, 2021 is an appropriate form of authorization for the purposes of meeting the FY 2022 new technology add-on payment eligibility requirements.

Response: We thank the applicant for their comment. With regard to the applicant's statement that market authorization, not approval, is the criterion for new technology add-on payment eligibility, as we noted in the proposed rule, we revised our regulations at § 412.87 in the FY 2009 IPPS final rule (73 FR 48561 through 48563) to codify our longstanding practice of how CMS evaluates the eligibility criteria for new technology add-on payment applications. We specifically stated that new technologies that have not received FDA approval do not meet the newness criterion. More recently, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742), we finalized a technical clarification to the language of § 412.87 to more precisely describe the various types of FDA approvals, clearances, licensures, and classifications that we consider under our new technology add-on payment policy. As we stated at that time, this technical clarification did not change or modify the policy set forth in existing § 412.87(e)(2). We explained that under our current policy, in evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, we consider whether the technology has received marketing

[296] The Federal Drug and Food Administration. Emergency Use Authorizations: Drug and Biological Products. 2020. *https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-useauthorization#coviddrugs.*

authorization by July 1 (such as Premarket Approval (PMA); 510(k) clearance; the granting of a De Novo classification request; or approval of a New Drug Application (NDA)). Accordingly, and consistent with our longstanding practice, we continue to consider FDA marketing authorization as representing that a product has received FDA approval or clearance for purposes of eligibility for the new technology add-on payment under § 412.87(e)(2).

In the FDA's press release regarding its issuance of an EUA for Olumiant™, it states that ''[t]he issuance of an EUA is different than an FDA approval.'' [297] To determine whether to issue an EUA, FDA ''evaluates the totality of available scientific evidence and carefully balances any known or potential risks with any known or potential benefits of the product for use during an emergency.'' This standard is different from the standard that FDA uses to evaluate whether to approve a drug. Therefore, we continue to believe that, for the purposes of new technology add-on payments, a product that is only available through an EUA is not considered to have FDA approval or clearance and therefore is not considered eligible for new technology add-on payments.

In response to the applicant's comment that an EUA should suffice for the new technology add-on payment's marketing authorization requirement because an EUA was sufficient for CMS to authorize payment enhancements for COVID–19 treatments under NCTAP, we note that there are distinct eligibility criteria for new technology add-on payment as compared to NCTAP. As noted previously, historically, CMS has stated that for the purposes of new technology add-on payments, that new technologies that have not received FDA approval do not meet the newness criterion. In addition to the newness criterion, there is a substantial clinical improvement criterion to qualify for new technology add-on payments that is not required for NCTAP. We have previously stated (73 FR 48561 through 48563) that we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective. For these reasons, we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. As stated by FDA in their November 19, 2020 news release announcing the issuance of the EUA for Olumiant®, ''the safety and effectiveness of this investigational therapy for use in the treatment of COVID–19 continues to be evaluated.'' [298] Therefore, while we believe that the FDA's issuance of an EUA for Olumiant® is sufficient to support NCTAP eligibility to ensure that providers are not disincentivized to provide this treatment to patients with COVID–19, we do not believe that it would be appropriate for us to make a determination whether Olumiant provides a substantial clinical improvement over existing technologies for the purposes of new technology add-on payments.

In response to the applicant's comment that CMS should harmonize its payment policies to ensure consistency and prevent lapses in reimbursement that could lead to access barriers for patients, we do not believe that our position that an EUA is not considered an FDA marketing authorization for the purpose of new technology add-on payments will lead to patient access issues. As discussed in section XXX of this final rule, we are finalizing our proposal to extend the NCTAP through the end of the fiscal year in which the PHE ends for all eligible products. This means that qualifying inpatient cases involving the use of Olumiant®, in combination with VEKLURY®, will continue to be eligible for NCTAP through the end of the fiscal year in which the PHE ends. Additionally, as stated in the IPPS/LTCH PPS proposed rule (86 FR 25395), if a product with an EUA receives FDA approval by July 1, 2022, it would be eligible for consideration of new technology add-on payments beginning FY 2023, and new technology add-on payments, if approved, would begin on October 1, 2022 (the beginning of FY 2023).

We refer the readers to section XXX of this final rule for a discussion of the comment solicitation including a summary of the comments received.

As stated previously, Olumiant® has an EUA and is indicated for use in combination with remdesivir for the treatment of suspected or laboratory confirmed COVID–19 in certain hospitalized patients requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). However, because Olumiant® did not receive FDA clearance or approval by July 1, 2021 for this indication, it is not eligible for consideration for new technology add-on payments for FY 2022 and therefore and we are not approving new technology add-on payments for Olumiant® for FY 2022. We note that we received public comments from the applicant regarding the substantial clinical improvement criterion. However, because Olumiant® is ineligible for consideration for new technology add-on payments for FY 2022 because it did not receive FDA clearance or approval by July 1, 2021, we are not summarizing nor responding to public comments regarding the substantial clinical improvement or cost criteria for this application in this final rule. Under our finalized policy as discussed in section XXX of this final rule, qualifying inpatient cases involving the use of Olumiant®, in combination with VEKLURY®, are currently eligible for NCTAP beginning November 19, 2020, the date Olumiant® received EUA, through the end of the fiscal year in which the PHE ends.

j. Pure-Vu® System

Motus GI holdings, Inc. submitted an application for new technology add-on payments for the Pure-Vu® System for FY 2022. The Pure-Vu® System is an FDA cleared system designed to connect to currently marketed colonoscopes to provide high intensity, intra-procedural cleansing of the colon during a colonoscopy. According to the applicant, the Pure-Vu® System is indicated for use in patients requiring therapeutic or diagnostic colonoscopies where the bowel has not been adequately prepared. The applicant asserted that the Pure-Vu® System would be used in situations such as a lower gastrointestinal bleed (LGIB), as LGIB does not allow for adequate bowel preparation.

The applicant asserted that the Pure-Vu® System device helps to avoid aborted and delayed colonoscopy procedures due to poor visualization of the colon mucosa by creating a unique High Intensity, Pulsed Vortex Irrigation Jet that consists of a mixture of air and water to break-up fecal matter, blood clots, and other debris, and scrub the walls of the colon while simultaneously removing the debris through two suction channels. The applicant stated that the suction channels have a sensor

[297] U.S. Food and Drug Administration. (2020, November 19). *Coronavirus (COVID–19) Update: FDA Authorizes Drug Combination for Treatment of COVID–19.* U.S. Food and Drug Administration. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-drug-combination-treatment-covid-19.*

[298] Ibid.

to detect the formation of a clog in the channels, triggering the system to automatically purge and then revert to suction mode once the channel is clear. According to the applicant, this combination of the agitation of the fluid in the colon via the pulsed vortex irrigation and simultaneous removal of the debris allows the physician to visualize the colon and achieve a successful colonoscopy or other advanced procedure through the colonoscope even if the patient is not properly prepped and has debris either blocking the ability to navigate the colon or covering the colon wall obscuring the mucosa and any pathology that may be present. The applicant asserted that the constant volume suction pumps do not cause the colon to collapse, which allows the physician to continue to navigate the colon while cleansing and avoids the need to constantly insufflate the colon, which may be required with other colonoscopy irrigation systems.

The applicant stated that the Pure-Vu® System is comprised of a workstation that controls the function of the system, a disposable oversleeve that is mounted on a colonoscope and inserted into the patient, and a disposable connector with tubing (umbilical tubing with main connector) that provides the interface between the workstation, the oversleeve, and off the shelf waste containers.

The applicant explained that the workstation has two main functions: Cleansing via irrigation and evacuation, and acting as the user interface of the system. The applicant explained that the irrigation into the colon is achieved by an electrical pump that supplies pressurized gas (air) and a peristaltic pump that supplies the liquid (water or saline). According to the applicant, the pressurized gas and liquid flow through the ''main connector'' and are mixed upon entry into the umbilical tubing that connects to the oversleeve. The applicant explained that the gas pressure and flow are controlled via regulators and the flow is adjusted up or down depending on the cleansing mode selected. The applicant stated that a foot pedal connected to the user interface activates the main functions of the system so that the user's hands are free to perform the colonoscope procedure in a standard fashion.

The applicant stated that the evacuation mode (also referred to as suction) removes fecal matter and fluids out of the colon. The applicant noted that the evacuation function is active during cleansing so that fluid is inserted and removed from the colon simultaneously. The applicant explained that the evacuation pumps are designed in a manner that prevents the colon from collapsing when suctioning, which facilitates the ability to simultaneously irrigate and evacuate the colon. According to the applicant, during evacuation, the system continuously monitors the pressure in the evacuation channels of the oversleeve and if the pressure drops below pre-set limits the pumps will automatically reverse the flow. The applicant explained that the clog sensor triggers the system to automatically purge the material out of the channel and back into the colon where it can be further emulsified by the Pulsed Vortex Irrigation Jet, and then automatically reverts back into evacuation mode once the channel is cleared. The applicant stated that the evacuation (suction) that drains fecal matter and fluids out of the colon is generated by peristaltic pumps that can rotate in both directions, either to evacuate fluids and fecal matter from the colon through the evacuation tubes and into a waste container, or while in the reverse direction, to purge the evacuation tubes. The applicant claimed the suction created by this type of pump creates a constant volume draw of material from the colon and therefore prevents the colon from collapsing rapidly. According to the applicant, purging of evacuation tubes may be activated in two ways: The purging cycle is automatically activated when low pressure is noted by the evacuation-line sensor (it is also activated for the first 0.5 seconds when evacuation is activated to make sure the line is clear from the start); or a manual purge may be activated by the user by pushing the ''manual purge'' button on the foot pedal. The applicant claimed the pressure-sensing channel is kept patent by using an air perfusion mechanism where an electrical pump is used to perfuse air through the main connector and into the oversleeve, while the sensor located in the workstation calculates the pressure via sensing of the channel.

The applicant explained the Pure-Vu® System is loaded over a colonoscope and that the colonoscope with the Pure-Vu® oversleeve is advanced through the colon in the same manner as a standard colonoscopy. The applicant stated that the body of the oversleeve consists of inner and outer sleeves with tubes intended for providing fluid path for the cleansing irrigation (2X), the evacuation of fluids (2X), the evacuation sensor (1X) and that the flexible head is at the distal end of the oversleeve and is designed to align with the colonoscope's distal end in a consistent orientation. The applicant explained that the distal cleansing and evacuation head contains the irrigation ports, evacuation openings, and a sensing port. According to the applicant, the system gives the physician the control to cleanse the colon as needed based on visual feedback from the colonoscope to make sure they have an unobstructed view of the colon mucosa to detect and treat any pathology. The applicant noted that since the Pure-Vu® System does not interfere with the working channel of the colonoscope, the physician is able to perform all diagnostic or therapeutic interventions in a standard fashion with an unobstructed field of view.

According to the applicant, multiple studies have shown that inadequate bowel visualization leads to missed pathology, delayed diagnosis, extended hospital stay, and in some cases, additional therapy being administered, especially in the acute LGIB population, which is the most common indication for inpatients that require colonoscopy.[299] [300] Unknown abdominal pain, infection, and foreign body removal were also cited by the applicant as being common indications for an inpatient colonoscopy.

The applicant explained that when a patient with LGIB is admitted to the hospital, they are stabilized and then started on bowel preparation for the colonoscopy procedure. The applicant claimed that the patient typically is placed on a liquid-only diet while consuming 4–6 liters of polyethylene glycol (PEG) based solution until the rectal effluent is clear. If the rectal effluent is not clear, additional bowel preparation is prescribed. The applicant stated that for severe LGIB cases, a patient is prescribed to consume a rapid purge of 1 liter every 30–45 minutes with a total volume of 4–14 liters, which could lead to purgative intolerance or vomiting. The applicant claimed that even in situations where bowel preparation has been completed, and clear rectal effluent while on a clear liquid diet has been confirmed, there are no guarantees that a patient's bowel is clean for a successful colonoscopy. The applicant submitted data from a study by the Cleveland Clinic showing 51 percent of 8,819 patients observed over a 4-year period were inadequately

[299] Garber A, Sarvepalli S, Burke CA, Bhatt A, Ibrahim M, McMichael J, et al. Modifiable Factors Associated with Quality of Bowel Preparation Among Hospitalized Patients Undergoing Colonoscopy. J Hosp Med. 2019;14(5):278–83.

[300] Yadlapati R, Johnston ER, Gregory DL, Ciolino JD, Cooper A, Keswani RN. Predictors of Inadequate Inpatient Colonoscopy Preparation and Its Association with Hospital Length of Stay and Costs. Dig Dis Sci. 2015;60(11):3482–90.

prepared for colonoscopies, leading to one extra day in the hospital compared to patients that were adequately prepared.[301] The applicant cited another study, by Northwestern University, demonstrating an association between inadequate bowel preparation and increased length of stay (LOS) in hospitals, with inadequately prepared patients staying two more days than adequately prepared patients on average.[302] The applicant claimed additional time spent in hospitals increases the patient's exposure to risks of hospital-acquired infections. The applicant claimed this risk is especially impactful to patients who are admitted for LGIB, which is seen at a higher prevalence in the elderly population.[303] [304] The applicant stated in the elderly population, continuous bowel preparation also poses increased risk due to their higher comorbidities and potential for electrolyte imbalances such as hyperphosphatemia, hypocalcemia, and hypokalemia.[305]

The applicant cited a practical guide authored by Kim B., et al., to assert that poor visualization of the colon mucosa has a direct effect on the ability to detect the presence of a GI bleed or the aftermath stigmata and administer treatment successfully.[306] The applicant used the Boston Bowel Preparation Scale (BBPS), developed by Lai E. et al.,[307] as a reliable method to measure bowel preparation. The applicant stated that the scale is a range (0–9) of dirtiest to cleanest for the whole colon and 0 to 3 for each of the 3 segments of the colon; the right colon (including the cecum and ascending colon), the transverse colon (including the hepatic and splenic flexures), and the left colon (including the descending colon, sigmoid colon, and rectum). Therefore, the maximum BBPS score for a perfectly clean colon without any residual liquid is nine and the minimum BBPS score for an unprepared colon is zero. The points are assigned as follows: zero = Unprepared colon segment with mucosa not seen due to solid stool that cannot be cleared; one = Portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen due to staining, residual stool and/or opaque liquid; two = Minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well; three = Entire mucosa of colon segment seen well with no residual staining, small fragments of stool or opaque liquid.

The applicant stated that evidence-based guidelines and clinical reviews in high impact biomedical journals recommend colonoscopy as the preferred initial modality for the diagnosis and treatment of acute lower gastrointestinal bleeding.[308] [309] The applicant stated that colonoscopy has been less frequently utilized than might otherwise be indicated because it suffers from the significant disadvantage of requiring the need for a large volume bowel preparation.[310] The applicant states that even with a bowel preparation, poor visualization often occurs because of a poorly prepared colon. Based on these assertions, the applicant inferred that colonoscopy for acute lower gastrointestinal bleeding would be much more utilized and lead to more diagnoses and interventions with intraprocedural bowel preparation, which puts the control of the visualization (cleanliness) of the colon mucosa in the hands of the endoscopist. The applicant further stated it is important to appreciate that alternatives to colonoscopy, including angiography and vascular embolization treatments to create hemostasis, have risks of ischemic vascular injury, retroperitoneal bleeding and acute renal injury.[311] The applicant stated that aside from the colonoscopy, other modalities such as tagged red blood cell scans, computed tomography (CT) angiograms, and mesenteric angiographies all require an active source of bleed in order to achieve a successful diagnostic yield. The applicant claimed that even when diagnosis is achieved using these modalities, a colonoscopy may still be ordered to treat the source of the bleed via epinephrine injections and clipping and thermal therapies, to prevent potential surgical interventions.

With respect to the newness criterion, the Pure-Vu® System first received FDA 510(k) clearance on September 22, 2016 under 510(k) number K60015. Per the applicant, this initial device was very cumbersome to set up and required direct support from the company and therefore was not viable for a small company with limited resources to market the device. The applicant noted that the initial device could have been sold starting on January 27, 2017 when the first device came off the manufacturing line. Per the applicant, the device was allocated for clinical evaluations but 10 institutions throughout the country purchased the device outside of a clinical study, primarily to allow physicians to try the product prior to committing to a clinical trial. The applicant further noted that minor modifications were made to the Pure-Vu System in additional 510(k) clearances dated December 12, 2017 and June 21, 2018. The current marketed Pure-Vu System was then granted 510(k) clearance on June 6, 2019 under 510(k) number K191220. Per the applicant, this clearance changed the entire set-up of the device, redesigned the user interface, and reduced the size, among other changes. According to the applicant, this updated version was commercially available as of September 19, 2019.

The applicant submitted a request for approval for a unique ICD–10–PCS code for the use of the Pure-Vu® System technology and was granted approval for the following procedure code effective October 1, 2021: XDPH8K7 (Irrigation of lower GI using intraoperative single-use oversleeve, via natural or artificial opening endoscopic, new technology group 7).

If a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and therefore would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant

[301] Garber A, Sarvepalli S, Burke CA, Bhatt A, Ibrahim M, McMichael J, et al. Modifiable Factors Associated with Quality of Bowel Preparation Among Hospitalized Patients Undergoing Colonoscopy. J Hosp Med. 2019;14(5):278–83.

[302] Yadlapati R, Johnston ER, Gregory DL, Ciolino JD, Cooper A, Keswani RN. Predictors of Inadequate Inpatient Colonoscopy Preparation and Its Association with Hospital Length of Stay and Costs. Dig Dis Sci. 2015;60(11):3482–90.

[303] Parra-Blanco A, Ruiz A, Alvarez-Lobos M, Amoros A, Gana JC, Ibanez P, et al. Achieving the best bowel preparation for colonoscopy. World J Gastroenterol. 2014;20(47):17709–26.

[304] Hauck K, Zhao X. How dangerous is a day in hospital? A model of adverse events and length of stay for medical inpatients. Med Care. 2011;49(12):1068–75.

[305] Parra-Blanco A, Ruiz A, Alvarez-Lobos M, Amoros A, Gana JC, Ibanez P, et al. Achieving the best bowel preparation for colonoscopy. World J Gastroenterol. 2014;20(47):17709–26.

[306] Kim BS, Li BT, Engel A, et al. Diagnosis of gastrointestinal bleeding: A practical guide for clinicians. World J Gastrointest Pathophysiol. 2014;5(4):467–478.doi: 10.4291/wjgp.v5.i4.467.

[307] Lai EJ, Calderwood AH, Doros G, Fix OK, Jacobson BC. The Boston Bowel Preparation Scale: A valid and reliable instrument for colonoscopy-oriented research. Gastrointestinal Endoscopy. 2009;69(3):620–625

[308] Strate LL, Gralnek IM. ACG Clinical Guideline: Management of Patients With Acute Lower Gastrointestinal Bleeding. Am J Gastroenterol. 2016 Apr;111(4):459–74. doi: 10.1038/ajg.2016.41. Epub 2016 Mar 1. Erratum in: Am J Gastroenterol. 2016 May;111(5):755. PMID: 26925883; PMCID: PMC5099081.

[309] Gralnek IM, Neeman Z, Strate LL. Acute Lower Gastrointestinal Bleeding. N Engl J Med. 2017 Mar 16;376(11):1054–1063. doi: 10.1056/NEJMcp1603455. PMID: 28296600.

[310] Carney BW, Khatri G, Shenoy-Bhangle AS. The role of imaging in gastrointestinal bleed. Cardiovasc Diagn Ther. 2019 Aug;9(Suppl 1):S88–S96. doi: 10.21037/cdt.2018.12.07. PMID: 31559156; PMCID: PMC6732104.

[311] Ibid.

asserted that the Pure-Vu® System has a different mechanism of action than existing technologies due to its ability to break up and remove a high volume of debris from the colon and dislodge adherent films from the colon wall in a safe manner that cannot be achieved with irrigation done through the working channel of a colonoscope. The applicant also asserted that due to the controlled simultaneous removal of the debris and fluid by the evacuation pumps in the system, the Pure-Vu® System eliminates the likelihood of creating a fluid load in the colon, which cannot be achieved with any other device on the market. The applicant further asserted a differing mechanism of action via the ability to sense and automatically clear a blockage versus manual suction through the working channel of a colonoscope, which can clog quickly if there is any appreciable debris. Lastly, the applicant explained that the Pure-Vu® System is an oversleeve device that allows use of the working channel of the colonoscope to be open and allows therapy to be administered in tandem with cleansing, unlike existing technologies on the market.

The applicant noted that the ClearPath system, a colonoscopy system by the company Easy Glide, received FDA clearance, but according to the applicant, was never fully brought to the US market. ClearPath was listed as the predicate device for the initial version of the Pure-Vu System® approved on September 22, 2016 (FDA 510(K) number K160015), in which both devices are described as able to irrigate and suction at any time during the procedure without any tools needing to be removed from the colonoscope working channel.[312] The applicant claimed that this system did not have the High Intensity Pulsed Vortex Irrigation Jet and controlled suction capabilities with the sensing and auto purge technology that is critical to get the desired clinical outcome.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that the Pure-Vu System is assigned to the same MS–DRGs as existing technologies. The applicant lists 21 MS–DRGs as being applicable, with MS–DRG 378 (gastrointestinal hemorrhage with complication or comorbidity (CC)) accounting for 37.1 percent of cases, and MS–DRG 377 (gastrointestinal hemorrhage with major complication or comorbidity (MCC)) accounting for 18.9 percent of total cases.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that the Pure-Vu System® does involve treatment of the same or similar type of disease and patient population as existing technology.

In the proposed rule, after reviewing the information submitted by the applicant, we noted that we were unclear whether the Pure-Vu® System's mechanism of action is similar to that of the version of the product that received initial 510(k) clearance that was approved on September 22, 2016 or other versions of the system. In addition, with regard to the previous versions of Pure-Vu®, we were unsure if the limited availability noted by the applicant would allow the technology to be considered commercially available. We were also unclear what the applicant meants regarding the ClearPath system being not fully brought to the U.S. market. We stated that if the ClearPath system and/or earlier versions of the Pure-Vu® System were considered to be available on the U.S. market, then we are concerned that the current version of Pure-Vu® would no longer be considered new, as we believe it may be substantially similar to ClearPath and/or earlier versions of the Pure-Vu® System because they also allow for irrigation and suction of the colon without utilizing the working channel. We stated that if the current version of Pure-Vu is substantially similar to ClearPath and/or previous versions, then it appeared that the current Pure-Vu system may no longer be within the newness period. We further noted that though the applicant states the Pure-Vu® System features a high intensity pulsed vortex irrigation jet and controlled suction capabilities with sensing and auto purge technology, the Pure-Vu® System irrigates the colon using water and gas like other existing irrigation methods. We were therefore uncertain as to whether these features of the Pure-Vu® System result in a new mechanism of action. We invited public comment on whether the Pure-Vu® System has a new mechanism of action compared to these predicate devices.

We invited public comments on whether the Pure-Vu® System is substantially similar to existing technologies and whether it meets the newness criterion.

Comment: The applicant submitted a letter that stated the Pure-Vu® System meets the newness criterion. The applicant provided clarifying information regarding the mechanisms of action of the Pure-Vu® System compared to its predicate device, the ClearPath system. The applicant stated that the predicate device, ClearPath, allowed for much higher fluid flow rates to raise irrigation pressure, whereas the Pure-Vu® System can mix gas into the fluid to create the pulsatile action of the irrigation jet with a lower fluid load in the colon. Additionally, the applicant stated that the Pure-Vu® System has the ability to simultaneously irrigate and suction fluid and debris, whereas the ClearPath system was only able to do one or the other, similar to a colonoscope. The applicant further stated that the Pure-Vu® System maintains a built-in suction system that uses a constant volume suction pump and autopurge functions that do not cause the colon to collapse, whereas the suction in the ClearPath system was the same as that of using the working channel of a colonoscope, which tends to collapse the lumen of the colon and, therefore, requires the endoscopist to continually insufflate the colon to provide patency and visualization. Finally, the applicant stated that the irrigation and suction in the Pure-Vu® System are self-contained (without need to plug into wall suction), whereas the ClearPath system needed to connect to the wall suction in the hospital room. The applicant stated that the flexibility of the Pure-Vu® System is beneficial in performing cases in the ICU where availability of vacuum ports can be problematic.

The applicant also addressed market availability by stating that early versions of the Pure-Vu® System after the original 510(k) in September 2016 were only sold on a limited basis as part of a beta launch to allow potential investigators to evaluate the Gen 1 Pure-Vu® System to determine if they would be interested in participating in clinical trials. The applicant stated that after initial feedback was received for the Gen 1 Pure-Vu® System, the company decided to not make the product available to the market until the system was redesigned. The applicant reiterated that the commercial version (Gen 2) was subsequently FDA cleared in June 2019 and became commercially available in September 2019.

Response: We appreciate the additional information from the applicant on whether the product meets the newness criterion. After consideration of the information submitted by the applicant in their

[312] FDA. 2016, September. Pure Vu System 510(k) premarket notification. Deparment of Health and Human Services. Accessed at *https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160015.pdf.*

comment and as part of its FY 2022 new technology add-on payment application for the Pure-Vu® System, we agree that the Pure-Vu® System has a new mechanism of action as compared to the ClearPath system and traditional colonoscopes because of the Pure-Vu® System's oversleeve design, which enable use of irrigation and suction while leaving the working channel available for therapeutic interventions, as well as the ability to simultaneously irrigate and suction fluid and debris. We note that the applicant did not respond to our concern with regard to whether the Pure-Vu System has a new mechanism of action as compared to the predicate version and therefore we believe the two versions are substantially similar as they both allow for simultaneous irrigation and suction of the colon without utilizing the working channel. Based on further information from the applicant regarding the market availability of the predicate version, it appears that the predicate Gen 1 version of the Pure-Vu System cleared in 2016 was available for sale on a limited basis. The applicant maintains that it was not on the market. Therefore, without additional information, we are unsure with regard to the appropriate date on which the newness period should begin and whether it is new for FY 2022. However, based on the information from the applicant, it appears that the predicate Gen 1 version of the Pure-Vu System cleared in 2016 was available for sale on a limited basis. The applicant maintains that it was not on the market. Therefore, without additional information, we are unsure with regard to the appropriate date on which the newness period should begin and whether it is new for FY 2022.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR claims data file with the FY 2019 Final Rule with Correction Notice IPPS Impact File to identify potential cases representing patients who may be eligible for treatment using the Pure-Vu® System. The applicant identified claims that reported an ICD–10–CM diagnosis code of ICD–10–CM Z12.11 (Encounter for screening for malignant neoplasm of colon), K92.2 (Gastrointestinal hemorrhage, unspecified), D50.0 (Iron deficiency anemia secondary to blood loss (chronic)), and C18*._[313] (malignant neoplasm of colon). The ICD–10–PCS procedure codes listed in following table were used to identify claims involving colonoscopy procedures.

ICD-10-PCS Code	Description
0DJD8ZZ	Inspection of lower intestinal tract, via natural or artificial opening endoscopic
0D5M8ZZ	Destruction of descending colon, via natural or artificial opening endoscopic
0D5N8ZZ	Destruction of sigmoid colon, via natural or artificial opening endoscopic
0D5L8ZZ	Destruction of transverse colon, via natural or artificial opening endoscopic
0D5K8ZZ	Destruction of ascending colon, via natural or artificial opening endoscopic
0W3P8ZZ	Control bleeding in gastrointestinal tract, via natural or artificial opening endoscopic

The claim search conducted by the applicant resulted in 163,236 claims mapping to 633 MS–DRGs. The applicant stated that MS–DRGs 377 (G.I. Hemorrhage W MCC), 378 (G.I. Hemorrhage W CC), and 379 (G.I. Hemorrhage W/O CC/MCC) were the most common MS–DRGs to which cases reporting the listed ICD–10–PCS codes were assigned. The applicant stated that the large number of DRGs to which these cases were assigned suggests that patients were admitted to the hospital for a wide variety of reasons, but during the course of their hospital stay the patients received a colonoscopy. According to the applicant, since GI bleeding is among the most common reasons for a patient needing an urgent colonoscopy, MS–DRGs 377–379 would be expected to be the most common MS–DRGs to which cases involving the Pure-Vu technology would be assigned. Lastly, the applicant did not have any data available to suggest any specific reasons why potential patients who would be eligible for the Pure-Vu technology would map to specific MS–DRGs identified based on the claims search, such as MS–DRG 291 (Heart Failure and Stroke).

The applicant determined an average unstandardized case weighted charge per case of $63,265.

The applicant did not remove charges for prior technology. The applicant stated that no prior technology is being replaced. The applicant then standardized the charges using the FY 2019 Final Rule with Correction Notice Impact File. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the new technology, the applicant used the national average CCR for the Supplies and Equipment cost center of 0.297 from the FY 2021 Final IPPS rule. The applicant calculated a final inflated average case-weighted standardized charge per case of $93,914, which exceeded the average case-weighted threshold amount of $63,265 by $30,649. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for the Pure-Vu® System, we noted that the MS–DRGs used in the cost analysis were not limited to those describing conditions likely to require a colonoscopy. For example, the applicant included cases

[313] Fourth character is required to describe specific location of neoplasm.

assigned to MS–DRG 291 (Heart Failure and Shock with MCC). When included in the cost analysis, the assumption made is that all 1,948 cases for heart failure also had a colonoscopy performed where the technology could have potentially been utilized. We questioned whether all cases identified by the applicant appropriately represent potential cases eligible for the Pure-Vu® System. We invited public comment on whether the Pure-Vu® System meets the cost criterion.

Comment: The applicant, submitted a comment in response to concerns on whether the Pure-Vu System® meets the cost criterion. Regarding whether all cases identified by the applicant in its original cost criterion analysis appropriately represent potential cases eligible for treatment with the Pure-Vu® System, the applicant noted that not every MS–DRG included in the cost analysis was necessarily gastrointestinal in nature. The applicant explained that this is because patients may be admitted to the hospital for a variety of diagnoses, any of which may eventually lead to colonoscopy. For instance, although not all cases assigned to MS–DRG 291 (Heart Failure and Shock with MCC) would require a colonoscopy, some cases did and were thus included in the applicant's original analysis.

To respond to CMS concerns about the clinical coherence of the selected MS–DRGs, the applicant submitted a revised cost criterion analysis that pared down the number of MS–DRGs to only the top 12 in terms of case volume. The applicant identified 106,770 cases across these twelve MS–DRGs. The applicant stated that, according to the ICD–10 data, although all of these cases would have received a colonoscopy during their hospital stay, only a small portion would have met the clinical criteria for needing the Pure-Vu® System. The applicant asserted that the revised analysis includes a more clinically coherent set of MS–DRGS with 9 of 12 specifically labeled for gastrointestinal use. The applicant stated that while MS–DRGs 871, 812, and 811 are not specific to gastrointestinal diagnoses, they encompass conditions that commonly lead to GI bleeds and the need for colonoscopy and are therefore, appropriate to include in this analysis. The applicant noted that the Pure-Vu® System continues to exceed the case-weighted threshold when the MS–DRGs included in the analysis are pared down, albeit by a smaller margin than in the original analysis.

Response: We thank the commenter for its input and its submission of the revised cost criterion analysis. After review of the comments received and information submitted by the applicant for FY 2022 new technology add-on payments, we agree that the Pure-Vu® System meets the cost criterion as the final inflated case-weighted standardized charge per case exceeded the case-weighted threshold under the revised analysis including only the top 12 MS–DRGs by volume. We believe the cases identified by the applicant using the top 12 MS–DRG's by volume more appropriately represents potential cases eligible for the Pure-Vu® System than all the cases in the MS–DRGs used in their initial cost analysis.

With respect to the substantial clinical improvement criterion, the applicant asserted that the Pure-Vu® System offers the ability to achieve rapid beneficial resolution of the disease process treatment by achieving rapid and full visualization of the colon, which will improve diagnostic yield and the effectiveness of treatment of diseases of the bowel. The applicant claimed that due to the Pure-Vu® System's ability to cleanse the colon during the colonoscopy procedure in conjunction with a standard bowel preparation, or with an enema (to allow entry into the rectum) and without any purgative based preparation, the technology allows for earlier intervention. The applicant stated that in the case of an LGIB, this will reduce bleeding by achieving more rapid hemostasis and reduce the overall length of stay in the hospital for a portion of this population. The applicant also asserted the technology reduces the subsequent diagnostic and, in some instances, therapeutic interventions by minimizing aborted and early repeat procedures due to poor visualization caused by inadequate preparation. The applicant stated that the system can provide cleansing and removal of fecal matter, blood and other debris while maintaining the visibility of the colonoscope's camera and availability of the working channel to apply critical therapies.

In support of its claims, the applicant submitted a self-sponsored, U.S.-based, multicenter, prospective, single arm study in the inpatient setting, analyzing 94 patients, 65 of which (68 percent) had a GI bleed.[314] Of the 94 patients (41 percent females/59 percent males), the mean age was 62 years. According to the applicant, the study's primary endpoint was the rate of improved bowel cleansing level from baseline to after use of the Pure-Vu® System per colon segment using the Boston Bowel Preparation Scale (BBPS). The BBPS score was recorded for each colorectal segment (left colon, transverse colon, and right colon segments) both prior to (baseline) and after colon cleansing with the Pure-Vu® System. An adequate cleansing level was *a priori* defined as a BBPS ≥2 in all evaluated colon segments. The study found that in 79 of the 94 patients (84 percent), the physician was able to successfully diagnose or rule out a GI bleed in the colon per the patients' colonoscopy indication using only the Pure-Vu® System. The analysis showed statistically significant visualization improvement in each colon segment after Pure-Vu® use with a mean BBPS score in the descending colon, sigmoid, and rectum of 1.74 pre-Pure-Vu® use and 2.89 post-Pure-Vu® use ($P<0.001$); in the transverse colon of 1.74 pre-Pure-Vu® use and 2.91 post Pure-Vu® use ($P<0.001$); and the ascending colon and cecum of 1.50 pre-Pure-Vu® use and 2.86 post Pure-Vu® use ($P<0.001$). The study found only 2 percent of cases where the diagnosis could not be achieved due to inadequate preparation. Overall, the 84 (89.4 percent) patients that received the Pure-Vu® System within the study improved BBPS scores from 38 percent (95 percent CI 28, 49) to 96 percent (95 percent CI 90, 99) in segments evaluated. The study noted one procedure related perforation which required surgical repair, and the patient was discharged 48 hours post operatively and recovered fully.

The applicant also provided three outpatient clinical studies to demonstrate the Pure-Vu® System's capability to convert patients to adequate preparation where preparation was previously inadequate, and the visualization was poor based on the BBPS. In the first study, Perez J., et al. conducted an outpatient prospective pilot study using the Pure-Vu® System.[315] The study observed 50 patients with poorly prepared colons undergoing colonoscopy at two outpatient clinical sites in Spain and Israel, respectively. The applicant claimed study patients underwent a reduced bowel preparation consisting of the following: No dried fruits, seeds, or nuts starting 2 days before the colonoscopy, a clear liquid diet starting 18 to 24 hours before colonoscopy, and

[314] Helmut Neumann ML, Tim Zimmermann, Gabriel Lang, Jason B. Samarasena, Seth A. Gross, Bhaumik Brahmbhatt, Haleh Pazwash, Vladimir Kushnir. Evaluation of bowel cleansing efficacy in hospitalized patient population using the pure-vu system. Gastrointestinal Endoscopy. 2019;89(6).

[315] Perez Jimenez J, Diego Bermudez L, Gralnek IM, Martin Herrera L, Libes M. An Intraprocedural Endoscopic Cleansing Device for Achieving Adequate Colon Preparation in Poorly Prepped Patients. J Clin Gastroenterol. 2019;53(7):530–4.

a split dose of 20mg oral bisacodyl. The study found the number of patients with an adequate cleansing level (BBPS ≥2 in each colon segment) increased significantly from 31 percent (15/49) prior to use of the Pure-Vu System (baseline) to 98 percent (48/49) after use of the Pure-Vu® System (P<0.001), with no serious adverse events reported.

In the second study provided by the applicant, van Keulen, et al. also conducted a single-arm, prospective study on 47 patients with a median age of 61 years in the outpatient setting in the Netherlands using the Pure-Vu® System.[316] Within the study, cecal intubation was achieved in 46/47 patients. This multicenter feasibility study found that the Pure-Vu® System significantly improved the proportion of patients with adequate bowel cleansing from 19.1 percent prior to the use of the Pure-Vu® System to 97.9 percent after its use (P<0.001) and median BBPS score (from 3.0 [IQR 0.0–5.0] to 9.0 [IQR 8.0–9.0]).

In the third study provided by the applicant that directly evaluated the Pure-Vu® System in a clinical setting, Bertiger G., *et al.* performed a United States-based single center, prospective, outpatient study investigating regimes of reduced outpatient bowel preparations, which included low doses of over-the-counter laxatives, and eliminating the typical 24 hour clear liquid diet restriction, which was replaced by a low residue diet the day before the procedure. In this study, 46 of a possible 49 patients received a colonoscopy, 8 of which took the over-the-counter laxative (''MiraLAX arm''), 21 patients ingested two doses of 7.5oz Magnesium Citrate (MgC) each taken with 19.5oz of clear liquid (''Mag Citrate 15oz arm''), and 18 patients ingested 2 doses of 5oz MgC taken with 16oz of clear liquid (''Mag Citrate 10oz arm''). Of the 46 subjects, 59 percent were males and there was a mean age of 61±9.48 years. The study found that each of the 3 study arms revealed significant differences in BBPS score between the baseline preparation and post-cleansing via Pure-Vu. All the preparation regimens resulted in inadequately prepped colons. Comparing the mean BBPS rating for both pre- and post- Pure-Vu® use, the MiraLAX arm was inferior (P <0.05) to both Mag Citrate arms. For the MiraLAX arm, the mean BBPS Score improved from 1.50 to 8.63. For the Mag Citrate 15oz arm, the mean BBPS score improved from 3.62 to 8.95. For the Mag Citrate 10oz arm, the mean BBPS Score improved from 4.76 to 9.0.

In addition to the retrospective studies provided, the applicant also submitted three case studies to highlight the various clinical presentations of LGIB with the use of the Pure-Vu® System. In the first case, the applicant presented a 71-year-old woman with multiple episodes of bloody bowel movements and low hemoglobin levels for 2 days after a screening colonoscopy where 8 polyps were removed. The applicant stated that the patient underwent a successful colonoscopy using Pure-Vu without standard inpatient bowel preparation within 5 hours, and in addition to expediting the colonoscopy, four significant post-polypectomy ulcers were found and clipped by allowing the physician to cleanse the area and place the clips simultaneously. The applicant claimed that since the Pure-Vu® System does not impact the use of the endoscope's working channel, the physician was able to cleanse the area as needed during the intervention to allow precise placement of the clips applied to achieve hemostasis and the patient was discharged that same day.

The applicant submitted another case example where a 52-year-old male was admitted from the emergency department to the ICU due to significant GI bleeding, hemorrhagic shock, and acute kidney injury (AKI) six days after a colonoscopy where nine polyps were removed, including two polyps greater than 2 cm. The applicant stated that angiographic control of the bleeding was not considered due to AKI with rising creatinine, and bedside colonoscopy was immediately performed with the Pure-Vu® System without any bowel prep. Per the applicant, the physician was able to visualize the entire colon to confirm all sources of bleeding and place two clips to obtain hemostasis, and the patient was downgraded out of the ICU that day and discharged from the hospital the following day.

In the third case study submitted by the applicant, a 64-year-old male was admitted to the ICU with one day of bright red blood per rectum (BRBPR) along with a complex set of disorders including but not limited to alcohol use disorder, heart failure with reduced ejection fraction of 30 percent, and multidrug resistant tuberculosis. The Pure-Vu® System was used to attempt to definitively identify the bleeding source in the ICU. The applicant stated that although no active sites of bleeding were seen, red blood was found in the entire colon, and the patient was transferred out of the ICU 2 days later and discharged 3 days after transfer to the floor. The applicant claimed that while the patient's bleeding had stopped by the time the colon was examined, the ability to directly visualize the entire colon using the Pure-Vu® System helped avoid a third CT angiography during this hospitalization and helped the physicians to confirm that prior coil embolization had not resulted in focal colonic ischemia. The applicant asserted that this case showed that the Pure-Vu® System can be used with minimal preparation, enabling rapid investigation of LGIB in a very complex patient. The applicant concluded that these case studies demonstrate that a change in patient management occurs when the option of the Pure-Vu® System is available, especially when there is an urgent or severe GI bleed, where circumstances where other procedures (such as CT angiography) are insufficient and the option to perform the colonoscopy sooner is preferred.

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for the Pure-Vu® System, we had stated the following concerns in the proposed rule (86 FR 25304). While the studies provided in support of the Pure-Vu® System measure improvement of bowel preparation using the BBPS, the applicant did not provide data indicating that the improved BBPS directly leads to improved clinical outcomes (for example, reduction of blood loss in LGIB or reduction of missed polyps) based on use of the Pure-Vu® System. Additionally, we noted that the applicant has not provided any studies comparing the efficacy of the Pure-Vu® System to other existing methods or products for irrigation in support of its claims that the product is superior at removing debris from the colon while simultaneously preventing the colon from collapsing, allowing use of the working channel, or improving outcomes. Furthermore, we noted that many of the provided studies were based on small sample sizes, which may affect the quality and reliability of the data provided in support of the technology. In addition, we noted that the methodology described in the provided studies often involved time to adequately prepare the colon and included outpatient planned procedures, which may not reflect the emergent situations that the applicant states the Pure-Vu® System is intended to address in the inpatient setting. We

[316] Van Keulen KE, Neumann H, Schattenberg JM, Van Esch AAJ, Kievit W, Spaander MCW, Siersema PD. A novel device for intracolonoscopy cleansing of inadequately prepared colonoscopy patients: a feasibility study. Endoscopy. 2019 Jan;51(1):85–92. doi: 10.1055/a–0632–1927. Epub 2018 Jul 11.

also noted that the Helmut, et al. study noted one procedure related perforation which required surgical repair and we invited public comments regarding the concern of procedure related perforation.

We invited public comments on whether the Pure-Vu® System meets the substantial clinical improvement criterion.

Comment: Several commenters provided specific examples of individual instances where the use of the Pure-Vu® System was beneficial for a particular patient, including some patients with unique challenges that the commenters stated could not have been addressed without the use of the Pure-Vu® System. A commenter, offering support, claimed the Pure-Vu® System can help shorten hospital stays and maximize access to their hospital's endoscopy unit and cited cost as a limiting factor for the Pure-Vu® System's continued use. A commenter, offering support, did not consider Pure-Vu® as a panacea for all poor bowel preparations and did not think it was an alternative to appropriate bowel cleansing in most patients but did think it can be a great addition and a useful tool in every endoscopy suite and that it provides clear clinical improvement in the appropriate patients.

Response: We appreciate all of the comments received related to the Pure-Vu® System and have taken them into consideration in making our determination of substantial clinical improvement.

Comment: The applicant submitted comments in response to CMS's concerns in the FY 2022 IPPS/LTCH PPS proposed rule regarding whether the Pure-Vu® System meets the substantial clinical improvement criterion. The applicant reiterated previously shared data from a study by the Cleveland Clinic showing 51 percent of 8,819 patients observed over a 4-year period were inadequately prepared for colonoscopies, leading to one extra day in the hospital compared to patients that were adequately prepared.[317]

The applicant also presented a recently published study of 94 patients that analyzed the ability of the Pure-Vu® System to improve visualization of the colon mucosa for hospitalized patients undergoing colonoscopy.[318] The study demonstrated improvement in BBPS between a baseline for the patients prior to cleansing with the Pure-Vu® System and following the cleansing, with 38% of patients showing adequate colon cleansing level before the use of Pure-Vu® and 96% following the use of Pure-Vu®. The applicant also provided information on the Pure-Vu® System's performance within individual segments of the colon from this same study.

In response to our concern that while the evidence presented demonstrated improvement in BBPS but did not provide data indicating that improved BBPS directly leads to improved clinical outcomes, the applicant provided a study demonstrating the correlation between the ability to visualize the mucosa and the ability to detect important pathology. The study generally demonstrated a linear increasing trend in advanced adenoma detection rates with improvement in BBPS.[319] Lastly, the applicant submitted a modeling study indicating that the Pure-Vu® System can generate cost savings to health systems on a per patient basis if used in the colorectal cancer screening and surveillance population.

Response: We thank the applicant for their comment and appreciate the additional data submitted to address our concerns. After review of all the data received to date, we continue to have concerns regarding the substantial clinical improvement criterion as noted in the FY 2022 IPPS/LTCH PPS proposed rule. Specifically, we remain concerned that the studies provided in support of the Pure-Vu® System measure improvement of bowel preparation using the BBPS but do not provide data indicating that the improved BBPS directly leads to improved clinical outcomes. In addition, the studies did not demonstrate outcomes in the emergent situations for which the Pure-Vu® System is intended to address. While an additional study provided by the applicant in their comment indicated a general link between improved BBPS and advanced adenoma detection rates, we note that the study occurred in patients undergoing screening colonoscopy, and did not include the use of Pure-Vu. We also remain concerned about the lack of studies comparing the Pure-Vu® System to other existing methods or products for irrigation in support of its claims that the product is superior at removing debris from the colon while simultaneously preventing the colon from collapsing, allowing use of the working channel, or improving outcomes.

After consideration of all the information from the applicant, as well as the comments we received, we are unable to determine that the Pure-Vu® System represents a substantial clinical improvement over existing technologies, and we are not approving new technology add-on payments for the Pure-Vu® System for FY 2022.

k. Rapid ASPECTS

iSchemaView (which is in the process of a name change to RapidAI) submitted an application for new technology add-on payments for Rapid ASPECTS for FY 2022. According to the applicant, Rapid ASPECTS is a computer-aided diagnosis (CADx) software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities using computed tomography (CT) image data. The applicant asserted that the software automatically registers images and segments and analyzes ASPECTS Regions of Interest (ROIs). According to the applicant, Rapid ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics. The applicant stated that the imaging features are then synthesized by an artificial intelligence algorithm into a single ASPECT Score.

The applicant stated Rapid ASPECTS is indicated for evaluation of patients presenting for diagnostic imaging workup with known Middle Cerebral Artery (MCA) or Internal Carotid Artery (ICA) occlusion, for evaluation of extent of disease. The applicant stated that extent of disease refers to the number of ASPECTS regions affected, which is reflected in the total score.

According to the applicant, the Rapid ASPECTS device provides information that may be useful in the characterization of early ischemic brain tissue injury during image interpretation (within 6 hours). The applicant stated Rapid ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS atlas definitions and atlas display including highlighted ROIs and numerical scoring. The applicant stated that Rapid ASPECTS is not intended for primary interpretation of CT images; it is used to assist physician evaluation.

[317] Garber A, Sarvepalli S, Burke CA, Bhatt A, Ibrahim M, McMichael J, et al. Modifiable Factors Associated with Quality of Bowel Preparation Among Hospitalized Patients Undergoing Colonoscopy. J Hosp Med. 2019;14(5):278–83.

[318] 2 Neumann H, Latorre M, Zimmerman T, Lang G, Samarasena J, Gross S, Brahmbhatt B, Pazwash H, Kushnir V. A multicenter, prospective, inpatient feasibility study to evaluate the use of an intra-colonoscopy cleansing device to optimize colon preparation in hospitalized patients: the REDUCE study. BMC Gastroenterol. 2021 May 22;21(1):232.

[319] Jain D, Momeni M, Krishnaiah M, Anand S, Singhal S. Importance of reporting segmental bowel preparation scores during colonoscopy in clinical practice. World J Gastroenterol. 2015 Apr 7;21(13):3994–9. doi:10.3748/wjg.v21.i13.3994. PMID: 25852286; PMCID: PMC4385548.

The applicant asserted Rapid ASPECTS has been validated in patients with known MCA or ICA occlusion prior to ASPECT scoring.

According to the applicant, when patients with a suspected stroke arrive at an emergency department, they are rapidly triaged to the CT scanner for a non-contrast CT (NCCT) and CT angiography (CTA). The applicant stated that CTA directly images large vessel occlusions and the NCCT can exclude brain hemorrhage and identify early signs of brain infarction. The applicant asserted that automated large vessel occlusion (LVO) detection software is now used at many sites to quickly identify LVOs on CTA and provide physicians with early notification that an LVO has been identified. The applicant stated that following identification of an LVO, the next imaging evaluation required is for a physician, typically a radiologist or neuroradiologist, to determine the ASPECT score by taking a close look at the NCCT for evidence of early infarct signs. The applicant stated that patients with an ASPECT score between 6 and 10 who meet clinical criteria for thrombectomy should receive thrombectomy as soon as possible, if treatment can occur within 6 hours of symptoms onset. The applicant asserted that for patients who present beyond 6 hours, a CT perfusion or MRI scan are required to identify which patients are eligible for thrombectomy.

The applicant stated approximately 800,000 primary (first-time) or secondary (recurrent) strokes occur each year in the U.S., with the majority being primary strokes (roughly 600,000). Of these strokes, approximately 87% are ischemic infarctions, 10% are primary hemorrhages, and 3% are subarachnoid hemorrhage.[320] According to the applicant, the incidence of stroke rapidly increases with age, doubling for each decade after age 55. The applicant asserted that among adults ages 35 to 44, the incidence of stroke is 30 to 120 in 100,000 per year, and for those ages 65 to 74, the incidence is 670 to 970 in 100,000 per year. Therefore, according to the applicant, the primary burden of stroke affects the Medicare-age population. The applicant stated the most disabling strokes are those due to large vessel occlusions (LVOs), and treatment of these strokes has the largest therapeutic benefits.[321]

The applicant stated that Rapid ASPECTS received FDA 510(k) clearance as a CADx software device on June 26, 2020 and provided a date of first installation of September 1, 2020. The applicant described Rapid ASPECTS as a machine learning-based automated software for assessment of ASPECTS. The applicant asserted that Rapid ASPECTS remains the only cleared ASPECTS software and the only stroke imaging software to receive a CADx clearance by the FDA. The legally marketed predicate device that Rapid ASPECTS is substantially equivalent to, per FDA, is QuantX,[322] which was granted De Novo authorization on July 19, 2017. QuantX is a CADx software device used to assist radiologists in the assessment and characterization of breast abnormalities using magnetic resonance (MR) image data and is indicated for evaluation of patients presenting for high-risk screening, diagnostic imaging workup, or evaluation of extent of known disease.[323]

We note the applicant submitted a request for approval of a unique ICD–10–PCS procedure code to identify use of the technology and was granted approval for the following procedure code effective October 1, 2021: XXE0X07 (Measurement of intracranial vascular activity, computer-aided assessment, new technology group 7). According to the applicant, this new ICD–10–PCS code would be reported in addition to the non-contrast CT using the appropriate code as listed in current coding systems.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted Rapid ASPECTS uses a new mechanism of action (machine learning) to assess CT scans and synthesize a single ASPECT score when compared to existing options which are limited to clinical assessment by a human reader. According to the applicant, this software remains the only FDA-cleared ASPECTS software and the only stroke imaging software to receive a CADx clearance by the FDA. The applicant asserted Rapid ASPECTS is fully automated and produces a score for each of the 10 ASPECTS regions, as well as a total score in approximately 2 minutes.

With regard to the second criterion, whether the technology is assigned to the same or a different MS–DRG, the applicant stated that cases involving Rapid ASPECTS would be assigned to the same MS–DRGs as cases involving patients confirmed with an eligible LVO by a positive CTA. According to the applicant, in these cases, the traditional clinical pathway requires a physician to determine the ASPECT score through an imaging evaluation. The applicant noted that Rapid ASPECTS may result in patients being assigned to a different MS–DRG depending on whether or not a mechanical thrombectomy is performed as a result of the Rapid ASPECTS results.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted Rapid ASPECTS addresses the current stroke population.

In summary, the applicant believes that Rapid ASPECTS is not substantially similar to other currently available therapies because Rapid ASPECTS uses a new mechanism of action (machine learning) to assess CT scans and synthesize a single ASPECT score. We stated in the proposed rule that we are unclear as to whether machine learning to assess CT scans and synthesize a single ASPECT score would represent a unique mechanism of action, or how the mechanism of action by which Rapid ASPECTS assesses stroke imaging is distinct from other automated stroke imaging analysis tools, or the traditional hospital workflow.

We stated that we continue to be interested in public comments regarding issues related to determining newness for technologies that use AI, an algorithm or software, as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58628). Specifically, we are interested in public comment on how these technologies, including devices classified as radiological computer aided triage and notification software and radiological computer-assisted diagnostic software, may be considered for the purpose of identifying a unique mechanism of action; how updates to AI, an algorithm or software would affect an already approved technology or a competing technology; whether software changes for an already approved technology could be

[320] Ovbiagele B, et al. Stroke Epidemiology: Advancing Our Understanding of Disease Mechanism and Therapy *Neurotherapeutics.* (2011) 8:319–329.

[321] Ovbiagele B, et al. Stroke Epidemiology: Advancing Our Understanding of Disease Mechanism and Therapy *Neurotherapeutics.* (2011) 8:319–329.

[322] Rapid ASPECTS 510(k) clearance letter from FDA: *https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200760.pdf.*

[323] QuantX De Novo decision summary from FDA: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170022.pdf.*

considered a new mechanism of action, and whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome is the same as an already approved AI new technology.

We invited public comments on whether Rapid ASPECTS is substantially similar to existing technologies, including specifically with respect to the mechanism of action, and whether it meets the newness criterion.

Comment: The applicant submitted comments responding to CMS's concerns regarding newness as indicated in the proposed rule. With respect to our concern as to whether machine learning to assess CT scans and synthesize a single ASPECT score would represent a unique mechanism of action, or how the mechanism of action by which Rapid ASPECTS assesses stroke imaging is distinct from other automated stroke imaging analysis tools, or the traditional hospital workflow, the applicant stated that it used the framework for AI/ML that is differentiated within the FDA product codes for diagnostic imaging products. Per the applicant, these codes reflect the mechanism of action and also how products may be interpreted in terms of performance both against a reference standard and in informing the clinician.

The applicant stated that ContaCT/Viz LVO was classified as (CADt) Computer Aided Triage and Notification as a mechanism of action. Per the applicant, products in this category have limitations in what the software may do; specifically, that it is limited to determining and notifying the end user of suspicion of a disease state. In contrast, more advanced implementations of AI/ML require the establishment of clinical utility which shows the device not only performs to specifications but provides some value in the clinical setting regarding the lesion under investigation. Per the applicant, Rapid ASPECTS is classified as CADe/x, which provides the added information of a standard of care score which goes beyond triage and notification to inform the end user regarding treatment decisions. Specifically, Rapid ASPECTS provides information to help determine if the patient is a candidate for treatment of the LVO or not, while the previously approved ContaCT only informs the end user of a suspicion but not the severity or extent of the disease. Furthermore, the applicant stated that Rapid ASPECTS normalizes the decision-making ability of physicians with different levels of expertise. The applicant emphasizes that Rapid ASPECTS allows the typical reader to perform at the level of an expert reader and that it is the only stroke related software product that has been cleared with the advanced CADe/x designation, both of which are novel features. It is also the only automated software for ASPECT score assessment that has been cleared by FDA with any designation.

The applicant also concurred with other commenters in stating that AI, an algorithm, or software should be evaluated for newness in the same way as CMS evaluates any other medical device applying for new technology add-on payment. That is, the commenters stated that human intelligence and human processes are not FDA approved or cleared technologies and should not be used as a comparator to evaluate whether Rapid ASPECTS, or any technology, meets the definition of newness. A commenter also noted that each of the AI technologies that applied for new technology add-on payments for FY 2022 are distinctly different in that the technologies focus on different patient populations and/or would be assigned to different MS–DRGs. This commenter stated, along with the applicant, that Rapid ASPECTS is different from other technologies in that it uses machine learning to evaluate head CT scans and develops a single ASPECTS score in patients with suspected stroke.

A commenter noted how updates to an AI, an algorithm or software would affect an already approved technology or a competing technology. This commenter noted a phenomenon known as ''model drift,'' which can occur over time due to changes in healthcare workflows, practices, populations, and data. The commenter explained that when this occurs, the underlying algorithm does not automatically change and adapt to the new inputs, but its output predictions can become less accurate over time. The commenter further noted that model drift can be detected using the same statistical analyses that rigorously tested the algorithm's initial training data inputs and output predictions to ensure that they are free of statistically significant variances or biases. The commenter stated that if the AI/Machine Learning model or the algorithms that comprise the model change over time, they ideally should be subjected to this extensive statistical testing regimen that occurred before its original deployment, and developers should gauge the nature and extent of any model drift that occurs and make slight modifications if possible that would allow for its continued use in clinical care.

Response: We thank the applicant for its input. After consideration of the comments received and information submitted by the applicant, at this time and given our ongoing consideration of assessing newness for technology that use AI, an algorithm or software, we agree that Rapid ASPECTS does not use the same or a similar mechanism of action to achieve a therapeutic outcome when compared to existing treatment because it provides information, and specifically a standard of care score that characterizes the severity and extent of an LVO, to inform the end user of treatment decisions. Therefore, we believe that Rapid ASPECTS is not substantially similar to an existing technology and meets the newness criterion.

We also thank the commenters for their input on determining newness for technologies that use AI, an algorithm or software, including the applicant's distinctions between devices classified as computer-aided triage and notification software (CADt) and computer-aided detection or diagnosis software (CADe/x), as discussed in the proposed rule. We will continue consider how these technologies may be used to identify a unique mechanism of action; how updates to AI, an algorithm or software would affect an already approved technology or a competing technology; whether software changes for an already approved technology could be considered a new mechanism of action, and whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome is the same as an already approved AI new technology, as we gain more experience in this area.

With respect to the cost criterion, the applicant provided three analyses: (1) A baseline analysis containing all cases reporting one of the targeted ICD–10–CM codes below as the principal diagnosis code for cerebral infarction that map to one of the applicant's targeted MS–DRGs; (2) an analysis limited to MS–DRGs with a case volume over 100; and (3) an analysis limited to MS–DRGs 023, 062, 064, 065, and 066, which per the applicant would reflect 80 percent of all stays. For the baseline analysis, the applicant first extracted all inpatient stays from the CY 2018 Limited Data Set Standard Analytic File (LDS SAF) that contained a principal ICD–10–CM diagnosis code for cerebral infarction. The applicant used the following ICD–10–CM diagnosis codes.

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An Inpatient Stay Must Have At Least One Of The Listed Cerebral Infarction Diagnosis Codes As A Principal Diagnosis Code To Be Included In The Analysis	
ICD-10-CM Code	**Description**
Cerebral Arteries	
I63.311	Cerebral infarction due to thrombosis of right middle cerebral artery
I63.312	Cerebral infarction due to thrombosis of left middle cerebral artery
I63.313	Cerebral infarction due to thrombosis of bilateral middle cerebral arteries
I63.319	Cerebral infarction due to thrombosis of unspecified middle cerebral artery (NOTE: Not a legitimate billing code)
I63.321	Cerebral infarction due to thrombosis of right anterior cerebral artery
I63.322	Cerebral infarction due to thrombosis of left anterior cerebral artery
I63.323	Cerebral infarction due to thrombosis of bilateral anterior cerebral arteries
I63.329	Cerebral infarction due to thrombosis of unspecified anterior cerebral artery (NOTE: Not a legitimate billing code)
I63.331	Cerebral infarction due to thrombosis of right posterior cerebral artery
I63.332	Cerebral infarction due to thrombosis of left posterior cerebral artery
I63.333	Cerebral infarction due to thrombosis of bilateral posterior cerebral arteries
I63.411	Cerebral infarction due to embolism of right middle cerebral artery
I63.412	Cerebral infarction due to embolism of left middle cerebral artery
I63.413	Cerebral infarction due to embolism of bilateral middle cerebral arteries
I63.421	Cerebral infarction due to embolism of right anterior cerebral artery
I63.422	Cerebral infarction due to embolism of left anterior cerebral artery
I63.423	Cerebral infarction due to embolism of bilateral anterior cerebral arteries
I63.431	Cerebral infarction due to embolism of right posterior cerebral artery
I63.432	Cerebral infarction due to embolism of left posterior cerebral artery
I63.433	Cerebral infarction due to embolism of bilateral posterior cerebral arteries
I63.442	Cerebral infarction due to embolism of left cerebellar artery
I63.511	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral artery
I63.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery
I63.513	Cerebral infarction due to unspecified occlusion or stenosis of bilateral middle cerebral arteries
I63.521	Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery
I63.522	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery
I63.523	Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior cerebral arteries
I63.531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery
I63.532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery
I63.533	Cerebral infarction due to unspecified occlusion or stenosis of posterior cerebral arteries

I66.01	Occlusion and stenosis of right middle cerebral artery not resulting in cerebral infarction
I66.02	Occlusion and stenosis of left middle cerebral artery not resulting in cerebral infarction
I66.03	Occlusion and stenosis of bilateral middle cerebral arteries
I66.11	Occlusion and stenosis of right anterior cerebral artery not resulting in cerebral infarction
I66.12	Occlusion and stenosis of left anterior cerebral artery not resulting in cerebral infarction
I66.13	Occlusion and stenosis of bilateral anterior cerebral arteries not resulting in cerebral infarction
I66.21	Occlusion and stenosis of right posterior cerebral artery, not resulting in cerebral infarction
I66.22	Occlusion and stenosis of left posterior cerebral artery, not resulting in cerebral infarction
I66.23	Occlusion and stenosis of bilateral posterior cerebral arteries
I66.3	Occlusion and stenosis of cerebellar arteries not resulting in cerebral infarction not resulting in cerebral infarction
I66.8	Occlusion and stenosis of other cerebral arteries not resulting in cerebral infarction
I67.1	Cerebral aneurysm. Nonruptured
I67.2	Cerebral atherosclerosis

The applicant then removed cases for hospitals that are not paid under the IPPS. The applicant also removed inpatient stays and their assigned MS–DRGs from its analysis where the assigned MS–DRG met any of the following conditions: (1) The MS–DRG is for a part of the body not related to the head; (2) the MS–DRG is a psychiatric MS–DRG, alcohol-related MS–DRG, or a catchall MS–DRG; (3) the MS–DRG has a very small number of cases; or (4) the MS–DRG is unlikely to involve an LVO. The applicant identified 66,990 cases mapping to 27 MS–DRGs, as listed in the following table, in descending order by volume:

MS-DRG	MS-DRG Title
065	Intracranial Hemorrhage or Cerebral Infarction w CC or TPA in 24 Hrs
064	Intracranial Hemorrhage or Cerebral Infarction w MCC
023	Craniotomy w Major Device Implant or Acute CNS Pdx w MCC or Chemotherapy Implant or Epilepsy w Neurostimulator
066	Intracranial Hemorrhage or Cerebral Infarction w/o CC/MCC
062	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia w Thrombolytic Agent w CC
024	Cranio w Major Dev Impl/Acute Complex CNS Pdx w/o MCC
061	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia w Thrombolytic Agent w MCC
027	Craniotomy & Endovascular Intracranial Procedures w/o CC/MCC
026	Craniotomy & Endovascular Intracranial Procedures w CC
025	Craniotomy & Endovascular Intracranial Procedures w MCC
063	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia w Thrombolytic Agent w/o CC/ MCC
068	Nonspecific CVA & Precerebral Occlusion w/o Infarct w/o MCC
038	Extracranial Procedures w CC
003	Ecmo or Trach w MV >96 Hrs or Pdx Exc Face, Mouth & Neck w Maj O.R.
037	Extracranial Procedures w MCC
093	Other Disorders of Nervous System w/o CC/MCC
092	Other Disorders of Nervous System w CC
004	Trach w MV >96 Hrs or Pdx Exc Face, Mouth & Neck w/oMaj O.R.
091	Other Disorders of Nervous System w MCC
034	Carotid Artery Stent Procedure w MCC
035	Carotid Artery Stent Procedure w CC
039	Extracranial Procedures w/o CC/MCC
071	Nonspecific Cerebrovascular Disorders w CC
067	Nonspecific CVA & Precerebral Occlusion w/o Infarct w MCC
070	Nonspecific Cerebrovascular Disorders w MCC
036	Carotid Artery Stent Procedure w/o CC/MCC
072	Nonspecific Cerebrovascular Disorders w/o CC/MCC

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The applicant then standardized the charges and applied the 2-year charge inflation factor of 13.2 percent used to adjust the outlier threshold determination (85 FR 59039). The applicant did not remove charges for prior technology, as the applicant believes Rapid ASPECTS does not eliminate or replace any prior technology or services. The applicant also noted that it did not remove charges related to the prior technology, as the applicant believes Rapid ASPECTS does not reduce costs during the inpatient stay.

The applicant then added charges for the technology. The applicant stated that it estimated the cost per case of Rapid ASPECTS using historical

utilization data gathered from its Rapid CTA module. The applicant anticipates Rapid ASPECTS will be used in the same hospital sites as Rapid CTA, which also provides the applicant with a baseline number of Medicare and non-Medicare patients who were identified with a suspected LVO. The applicant estimated that approximately 20.5 percent of all patients who received a RAPID CTA scan qualified as inpatients eligible for a Rapid ASPECTS scan. The applicant divided the total number of qualified Medicare and non-Medicare inpatients by the total number of subscriber hospitals to arrive at an average number of inpatients eligible to be scanned with Rapid ASPECTS per subscriber hospital per year. The applicant then took the estimated average sales price per annual contract of Rapid ASPECTS per hospital and divided it across the estimated annual number of Rapid ASPECTS inpatients per site to estimate the average cost per case per subscriber hospital. Finally, the applicant divided the average cost per case by the national average CCR for radiology of 0.136 (85 FR 58601).

The applicant calculated a case-weighted threshold amount of $76,398 and a final inflated average case-weighted standardized charge per case of $90,097. Based on this analysis, the applicant asserted that Rapid ASPECTS meets the cost criterion because the final inflated average case-weighted standardized charge per case exceeds the case-weighted threshold amount. The applicant submitted two additional scenarios to demonstrate that the technology meets the cost criterion using the same methodology described but with limits on the cases. The first scenario limited the analysis to MS–DRGs with at least 100 cases. This resulted in a case-weighted threshold of $76,457 and a final inflated average case weighted standardized charge per case of $90,172. The second scenario limited the analysis to MS–DRGs 023, 062, 064, 065, and 066, which per the applicant reflect 80 percent of all stays. This second alternative method resulted in a case-weighted threshold of $67,890 and a final inflated average case-weighted standardized charge per case of $77,614. Across all three analyses, the applicant maintained that the technology meets the cost criterion because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount.

We noted the following concerns in the proposed rule regarding the cost analysis for Rapid ASPECTS. The applicant stated it removed from its analysis those cases and their assigned MS–DRG where the assigned MS–DRG was for a body part that is not the head; however, the list of MS–DRGs the applicant presented included MS–DRGs 37 (Extracranial Procedures w/MCC) and 38 (Extracranial Procedures w/CC), which by definition describe procedures outside of the head. We stated that we would like to understand why these MS–DRGs and their assigned cases were included in the baseline analysis. We stated that we would also like to understand the time period of the claims the applicant selected from the CY 2018 SAF, as this could have implications for the inflation factor used to update charges if the applicant selected claims from FY 2018 as opposed to FY 2019.

We stated that the applicant appears to have used a single list price of Rapid ASPECTS per hospital with a cost per patient that can vary based on the volume of cases. We noted that the cost per patient varies based on the utilization of the technology by the hospitals. The cost per patient could be skewed by the small number of hospitals utilizing the technology and their low case volumes. It is possible, if hospitals with large patient populations adopt Rapid ASPECTS, the cost per patient would be significantly lower.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58630), we stated our understanding that there are unique circumstances to determining a cost per case for a technology that utilizes a subscription for its cost. We stated our intent to continue to consider the issues relating to the calculation of the cost per unit of technologies sold on a subscription basis as we gain more experience in this area. We stated that we continue to welcome comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

We invited public comment on whether Rapid ASPECTS meets the cost criterion.

Comment: The applicant submitted comments addressing our concerns regarding whether Rapid ASPECTS meets the cost criterion. With respect to our inquiry regarding why cases assigned to MS–DRGs 37 (Extracranial Procedures w/MCC) and 38 (Extracranial Procedures w/CC) were included in the baseline, the applicant explained that it may be possible that some cases are assigned to those MS–DRGs after a full accounting of their diagnosis and reason for inpatient stay. The applicant provided the example of a blocked carotid artery delivering blood to the brain, which can be a cause of stroke. The applicant suggested that because the blockage occurred outside of the brain, these cases could be assigned to MS–DRG 37 or 38.

The applicant also provided an additional scenario for the cost threshold analysis that excluded MS–DRGs 37 and 38. The applicant re-ran its analysis with 2018 calendar year data to exclude MS–DRGs 37 and 38 and found that Rapid ASPECTS continues to satisfy the NTAP new technology add-on payment cost criterion, as seen below.

Summary new technology add-on payment charge threshold analysis for ASPECTS - 2018 Data

Scenario	Total Cases	Charge Threshold FY 2022	Standardized Charge Per Case
Updated Rapid ASPECTS Baseline to Remove MS-DRGs 37, 38	**66,308**	**$76,307**	**$89,499**
Updated sensitivity analysis 1: Limit to MS-DRGs with at least 100 cases but remove MS-DRGs 37, 38	66,094	$76,366	$89,572
Sensitivity analysis 2: Limit to MS-DRGs 023, 062, 064, 065, 066 which are responsible for 80% of all stays	53,648	$67,890	$77,614

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With respect to our inquiry regarding the time period of the claims the applicant selected for the CY 2018 SAF, the applicant stated that it used all relevant discharges during the 2018 calendar year (January 1st 2018—December 31st 2018). The applicant explained that for standardizing charges it used information specific to each hospital for the applicable fiscal year. The applicant explained that for claims with discharge dates from January 1st 2018 through September 30th 2018, it used cost-to-charge ratios, IME, DSH, wage-index, GAF, and COLA information specific to each hospital for FY 2018. The applicant further explained that, for claims with discharge dates from October 1st 2018 through December 31st 2018, it used cost-to-charge ratios, IME, DSH, wage-index, GAF, and COLA information specific to each hospital for FY 2019. The applicant also noted that, to maintain a conservative approach, it used an inflation factor of 13.22% for all discharges in the 2018 calendar year, even though it would be reasonable to use a higher inflation factor for claims with a discharge date prior to October 1st 2018.

With respect to our concern that the cost per patient for Rapid ASPECTS can vary based on the volume of cases, and that the applicant's cost per case may be skewed by the small number of hospitals utilizing the technology and their low case volumes, the applicant stated that although the cost per patient for Rapid ASPECTS may be lower for hospitals with high utilization of the technology, it will also be higher for hospitals with lower utilization. The applicant also stated that Rapid ASPECTS can help save lives, and that it is important to ensure that hospitals have equitable access to this technology to conform to current AHA guidelines and address an unmet need. The applicant's comments agreed with other commenters that responded to our request for comments regarding technologies sold on a subscription basis and whether the cost per case should be estimated based on subscriber hospital data, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment. Most commenters agreed that in determining the cost per case for technologies seeking new technology add-on payment that utilize a subscription model, we should limit our analysis to subscriber hospitals and update the cost analysis on an annual basis. A commenter noted that alternative methodologies involving estimating the number of patients who would be eligible to receive treatment utilizing a technology sold on a subscription basis would be likely to result in a payment amount that does not adequately reflect the estimated average cost of such service or technology as required by the statute. The commenter believes that given the direct impact of utilization changes on cost per case when using a subscription model, it is reasonable for CMS to annually update the payment amount using the most recent subscriber utilization data.

Response: We thank the commenter for its input. We appreciate the

explanation behind the inclusion of MS–DRG 37 and 38 in the applicant's original cost analysis and understand that stroke cases may be assigned to extracranial MS–DRGs after a full accounting of the patient's diagnosis and reason for inpatient stay. We also appreciate the additional information pertaining to the time period of the data used in the applicant's cost analysis submitted with its FY 2022 new technology add-on payment application and agree with the alignment of cost-to-charge ratios, IME, DSH, wage-index, GAF, and COLA information specific to each hospital with the respective fiscal year in which the discharge date falls. We agree with the applicant that, under the scenarios presented in its original application and in response to the FY 2022 IPPS/LTCH PPS proposed rule, the final inflated case-weighted standardized charge per case exceeded the case-weighted threshold and Rapid ASPECTS meets the cost criterion.

We also appreciate the applicant's comments relating to calculation of the cost per unit of technologies sold on a subscription basis. CMS will continue to consider the issues relating to calculation of the cost per unit of technologies sold on a subscription basis, including the merits of calculating the cost per case across all IPPS hospitals versus limiting the cost per case analysis to current users and whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment, as we gain more experience in this area.

With respect to the substantial clinical improvement criterion, the applicant asserted Rapid ASPECTS represents a substantial clinical improvement over existing technologies because it improves diagnostic decisions by improving accuracy of ASPECT scoring. The applicant also asserted it improves diagnostic decisions by reducing inter-rater variability of ASPECT scoring. The applicant also asserted it represents a substantial clinical improvement by improving treatment decisions and by improving time to treatment.

According to the applicant, the first stroke treatment, tissue plasminogen activator (tPA), was first approved in the United States for intravenous administration to patients with acute stroke in 1996, and a study demonstrating successful catheter-directed intra-arterial infusion of a thrombolytic agent for this indication was first published in 1999.[324] The applicant asserted that the first positive randomized controlled studies using modern mechanical thrombectomy devices for LVO stroke were published in 2015 and support combined treatment with tPA and catheter-based thrombectomy as the most effective treatment approach for patients who can be treated within six hours of symptom onset.[325] According to the applicant, following the publication of these trials, the American Heart Association (AHA) and American Stroke Association (ASA) released new guidelines in 2016, 2018 and 2019 that all specified the following Level 1A recommendation:

Patients should receive mechanical thrombectomy with a stent retriever if they meet all the following criteria:

- Pre-stroke modified Rankin Score (mRS) score of 0 to 1.
- Causative occlusion of the internal carotid artery (ICA) or middle cerebral artery (MCA) segment 1 (M1).
- Age ≥18 years.
- NIH Stroke Scale (NIHSS) score of ≥6.
- Alberta stroke program early CT score (ASPECTS) of ≥6.
- Treatment can be initiated (groin puncture) within 6 hours of symptom onset.[326]

According to the applicant, the previously recommended guidelines from the AHA/ASA have been widely accepted and outline the key requirements that are still used today to select early window (less than 6 hours) candidates for thrombectomy. The applicant asserted the imaging requirements (the second and the fifth criterion) require that patients be screened for an LVO with CTA and then once an LVO in the ICA or MCA is discovered, the ASPECTS score must be assessed to verify that it is 6 or higher. According to the applicant, the ASPECTS score is an assessment of the CT scan in a stroke patient to determine if there is evidence of irreversible injury in ten different brain regions. The applicant stated that patients who have more than five regions that are already irreversibly injured are not candidates for thrombectomy.

According to the applicant, it is well validated in the stroke literature that faster treatment leads to better outcomes. The applicant stated that compared with the best medical therapy alone, in the first five positive LVO endovascular thrombectomy trials that were published in the New England Journal of Medicine and subsequently summarized in a pooled analysis by the HERMES group, thrombectomy was associated with improved outcomes when procedure start (arterial puncture) could be performed within the first 7.3 hours after symptom onset among patients meeting the brain imaging entry criteria for inclusion in these randomized trials.[327] The applicant asserted that within this period, functional outcomes were better the sooner after symptom onset that endovascular reperfusion was achieved, emphasizing the importance of programs to enhance patient awareness, out-of-hospital care, and in-hospital management to shorten symptom onset-to-treatment times. The applicant asserted that the magnitude of the association between time to treatment and outcome is clinically meaningful. According to the applicant, in patients with acute ischemic stroke due to LVO, among every 1000 patients achieving substantial endovascular reperfusion, for every 15-minutes faster emergency department door–to-reperfusion time, an estimated 39 patients would have a less-disabled outcome at 3 months, including 25 more who would achieve functional independence (mRS 0–2).[328] The applicant stated that in addition to faster time from emergency department door to reperfusion, faster time from brain imaging to reperfusion was associated with better 3-month functional outcomes.[329]

According to the applicant, the interpretation of early infarct signs in CT first became clinically important following the FDA approval of tPA for stroke treatment in 1996 because it was shown that the response to tPA could be

[324] Furlan A, Higashida R, et al. Intra-arterial prourokinase for acute ischemic stroke: The PROACT II study: A randomized controlled trial: Prolyse in Acute Cerebral Thromboembolism. *JAMA.* 1999;282:2003–2011.

[325] Goyal M, Menon BK, et al. for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[326] Powers WJ, Rabinstein A, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418.

[327] Goyal M, Menon BK, et al. for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[328] Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[329] Ibid. Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

predicted based on the degree of early brain injury that could be visualized on the CT scan. The applicant asserted it was clear that intravenous tPA could be harmful in patients with advanced early infarct signs because they had a high risk of intracranial hemorrhage. The applicant stated, however, only rough qualitative estimates of the degree of early infarct signs were performed. The applicant asserted stroke clinicians generally felt believed it to be safe to give tPA if the early infarct signs were confined to less than one-third of the middle cerebral artery territory.[330]

According to the applicant, beginning in the 2000s, a more detailed and quantitative analysis of early infarct signs was proposed: The Alberta Stroke Program Early CT score (ASPECTS).[331] The applicant stated this score requires the evaluation of 10 pre-defined MCA vascular territories. The applicant asserted these individual regions are assessed for focal hypoattenuation of the cortex and in the basal ganglia, reduction of gray and white matter differentiation, and the loss of the insular ribbon sign. According to the applicant, ASPECTS is calculated by subtracting 1 point for each involved region; scores less than 6 typically signify patients with an irreversible large hemispheric infarction.[332]

According to the applicant, the ASPECTS evaluation became clinically essential in 2015 after mechanical thrombectomy was found to be effective for treatment of patients with a large vessel occlusion within the 6-hour time frame.[333] [334] The applicant stated that some of the large randomized controlled trials that ultimately led to the establishment of thrombectomy as a standard procedure required an ASPECTS greater than or equal to 6 for inclusion. According to the applicant, the MR CLEAN trial, which enrolled patients with lower ASPECT scores than the other four trials, reported the smallest overall treatment effect and in particular, patients with an ASPECT score less than 5 did not show benefit with an adjusted odds ratio close to 1.0.[335] The applicant asserted that for these reasons, an ASPECTS evaluation is required in most national and international thrombectomy guidelines. The applicant stated most guidelines, including the AHA/ASA guidelines discussed previously, require an ASPECT score greater than or equal to six 6 for a patient to qualify for thrombectomy in the early treatment window.[336]

The applicant asserted ASPECT score determination is challenging because early infarct signs are often very subtle and challenging to interpret correctly. According to the applicant, there is often disagreement between experts on the exact score and sometimes these disagreements preclude a definite answer regarding if the patient qualifies for thrombectomy or not. The applicant asserted these interpretation challenges are manifested by limited inter-rater agreement, even among experts.[337] [338] [339] The applicant cited the DEFUSE 2 study in which two expert readers graded ischemic change on NCCT using the ASPECT score. The applicant asserted that full-scale agreement (measured by the intraclass correlation coefficient) for CT–ASPECTS was only moderate at 0.579.[340] According to the applicant, these inter-rater differences can have important clinical implications, as discussed further. The applicant asserted that many physicians who evaluate acute stroke patients are not confident that they can accurately determine an ASPECT score, and oftentimes there are significant delays before a radiologist reads the scan. The applicant stated current AHA/ASA guidelines recommend a CT scan be performed within 25 minutes of Emergency Department arrival and the radiologist interpretation of the scan occur within 45 minutes of arrival.[341] According to the applicant, based on these guidelines, radiologists have about 20 minutes to read the scan, however, many hospitals, especially community and primary stroke centers, do not meet these guidelines. The applicant asserted Medicare data indicate that only 72% of patients meet these guidelines. The applicant stated that automated software, such as Rapid ICH, Rapid LVO and Rapid ASPECTS can assess CT and CTA findings (both to rule out hemorrhage, confirm an LVO and to assess early signs of infarction with ASPECTS) within minutes.

According to the applicant, the limited inter-rater agreement for traditional ASPECT scoring can lead to triaging ineligible patients to thrombectomy or failing to treat eligible patients. The applicant cited a study in which four experienced readers rated ASPECT scores in patients who presented with LVO and severe strokes. The applicant stated the inter-rater agreement between these raters was poor with an interclass correlation of 0.32.[342] According to the applicant, the range of agreement for individual raters with the gold standard assessment of the score (obtained with a concurrent MRI) for identifying patients with a score less than six 6 ranged from 35% to 94%. The applicant asserted this study demonstrates there can be substantial disagreement between physicians regarding if a patient is eligible for thrombectomy based on their assessment of the ASPECT score, which can lead to eligible patients not receiving this highly effective therapy, as well as the performance of unnecessary procedures.

The applicant asserted that particularly the Medicare population might be at risk and impacted by these

[330] von Kummer R, Allen KL, Holle R, et al. Acute stroke: Usefulness of early CT findings before thrombolytic therapy. *Radiology* 1997; 205:327–33.

[331] Barber PA, Demchuk AM, et al. Validity and reliability of a quantitative computed tomography score in predicting outcome of hyperacute stroke before thrombolytic therapy. ASPECTS Study Group. Alberta Stroke Programme Early CT Score. *Lancet.* 2000 May 13;355(9216):1670-4.

[332] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[333] Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[334] Powers WJ, Rabinstein A, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418.

[335] Berkhemer OA, Fransen PS, et al; MR CLEAN Investigators. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med.* 2015;372:11–20.

[336] Powers WJ, Rabinstein A, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418.

[337] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[338] Kobkitsuksakul C, Tritanon O, Suraratdecha V. Interobserver agreement between senior radiology resident, neuroradiology fellow, and experienced neuroradiologist in the rating of Alberta Stroke Program Early Computed Tomography Score (ASPECTS). *Diagn Interv Radiol.* 2018.

[339] McTaggart RA, Jovin TG, Lansberg MG, et al. Alberta stroke program early computed tomographic scoring performance in a series of patients undergoing computed tomography and MRI: Reader agreement, modality agreement, and outcome prediction. *Stroke.* 2015 Feb;46(2):407–12.

[340] McTaggart RA, Jovin TG, Lansberg MG, et al. Alberta stroke program early computed tomographic scoring performance in a series of patients undergoing computed tomography and MRI: Reader agreement, modality agreement, and outcome prediction. *Stroke* 2015 Feb;46(2):407–12.

[341] AHA/ASA. Target: Stroke Campaign Manual, published 2010. *http://www.strokeassociation.org/idc/groups/heart-public/@wcm/@hcm/@gwtg/documents/downloadable/ucm_308277.pdf.*

[342] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients with Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

limitations as the majority of LVOs occur in the Medicare population. The applicant stated that the average age of patients in the HERMES pooled analysis of thrombectomy studies was 68 years.[343] Therefore, according to the applicant, inaccuracy of traditional ASPECT scoring translates into a substantial percentage of Medicare patients having erroneous triage decisions made regarding their eligibility for thrombectomy, which it asserted can result in unnecessary procedures and increased Medicare costs, as well as increased disability in eligible patients who are not treated because of inaccurate ASPECT scoring.

As stated previously, the applicant asserted Rapid ASPECTS represents a substantial clinical improvement over existing technologies because it improves diagnostic decisions by improving accuracy of ASPECT scoring. The applicant presented three retrospective cohort studies (two peer-reviewed and one under review) to support the claim that diagnostic decisions made by clinicians would have been improved with use of Rapid ASPECTS. According to the applicant, two of the studies showed that the automated Rapid ASPECTS score is significantly more accurate than the scores obtained by experienced clinicians.[344] [345]

The applicant submitted a retrospective cohort study which compared ASPECT scoring of CT images from patients with MCA occlusion (n=100) between Rapid ASPECTS software and two expert neuroradiologist reads. According to the applicant, Rapid ASPECTS showed a substantial agreement (k=0.78) when imaging took place more than 1 hour after symptom onset, which increased to high agreement (k=0.92) for imaging occurring after 4 hours. The applicant asserted that the neuroradiologist raters did not achieve comparable results to the software until the time interval of greater than 4 hours (k=0.83 and k=0.76). In this study, experts developed the reference consensus score and then, after 6 weeks, the same two neuroradiologists again determined ASPECTS by using only the baseline CT. The experts had moderate agreement with the consensus score (k=0.57 and k=0.57) while Rapid ASPECTS had better agreement (k=0.9). There was minimal agreement across experts and software in the timeframe of less than 1 hour between symptom onset and imaging, but better software agreement when the time was between 1 and 4 hours. There was agreement across experts for imaging occurring after 4 hours. According to the applicant, this study showed that in acute stroke of the MCA, Rapid ASPECTS had better agreement than that of human readers with a predefined consensus score.[346]

The applicant submitted another retrospective cohort study to compare Rapid ASPECTS, as well as the mean score from four experienced readers, with a diffusion-weighted magnetic resonance imaging (DW–MRI) ASPECTS obtained following the baseline CT in patients (n=65) with large hemispheric infarcts.[347] DW–MRI is sensitive in the detection of small and early infarcts. Small infarcts might not appear on CT scans for days. The AHA/ASA guidelines state that DW–MRI can be useful for selecting candidates for mechanical thrombectomy between 6 and 24 hours after the patient was last known well (that is, the time at which the patient was known to be without signs and symptoms of the current stroke).[348]

According to the applicant, Rapid ASPECTS' automated score had a higher level of agreement with the mean of the DW–MRI ASPECTS, both for the full scale and for the dichotomized scale of either <6 or ≥6 which is the difference for treatment/no treatment (difference in intraclass correlation coefficient, p<0.001). The applicant stated that the mean DW–MRI ASPECT score was <6 in 63/65 (97%) of the cases; of these, RAPID ASPECTS agreed with the DW–MRI score in 46/63 (73%) of the cases (95% confidence interval [CI] 60–83%) vs. 35/63 56% of the cases (95% CI 44–69%) for the median score of the two experienced readers (p=0.027). The range of agreement for individual clinician CT ASPECTS with the median DW–MRI score for identifying patients with a score <6 was 35% to 94%. According to the applicant, this study demonstrated the accuracy for determining which patients have an ASPECTS <6 (which would exclude them from thrombectomy) was significantly higher with the software.[349]

The applicant submitted an additional retrospective cohort study under review for publication which compared physicians' (two expert neuroradiologists and six typical readers) ability to read ASPECTS in patients with an LVO (n=50; 10 regions in each patients' scan for a total of 500 individual regions) within 6 hours of symptom onset when assisted by Rapid ASPECTS, compared with their unassisted score. The applicant stated that the average ASPECT score of three additional experienced neuroradiologists who were provided access to a follow-up MRI was used as the reference standard. The applicant asserted that when typical readers read the scan in conjunction with the Rapid ASPECTS software, their agreement with the expert reads improved from 72% to 78% (p< 0.0001, test of proportions). According to the applicant, Rapid ASPECTS alone achieved correlations for total ASPECT scores that were similar to the three experienced neuroradiologist readers who had access to a follow-up MRI scan to help enhance the quality of their reads. The applicant asserted the results from this study showed that the aid of Rapid ASPECTS can significantly improve typical readers' scores and that the automated scores generated by Rapid ASPECTS are interchangeable with the scores generated by expert neuroradiologists.[350]

As stated previously, the applicant asserted Rapid ASPECTS represents a substantial clinical improvement over existing technologies because it improves diagnostic decisions by reducing inter-rater variability of ASPECT scoring. To support this claim the applicant submitted the study performed by iSchemaView and analyzed by an independent statistician that led to the FDA clearance of Rapid ASPECTS. According to the applicant, acute CT scans in patients with LVO (n=50) were read by eight readers both with and without Rapid ASPECTS. The

[343] Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[344] Maegerlein C, Fischer J, Mönch S, MD et al. Automated Calculation of the Alberta Stroke Program Early CT Score: Feasibility and Reliability. *Radiology* 2019; 291:141–148.

[345] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[346] Maegerlein C, Fischer J, Mönch S, MD et al. Automated Calculation of the Alberta Stroke Program Early CT Score: Feasibility and Reliability. *Radiology* 2019; 291:141–148.

[347] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[348] Powers WJ, Rabinstein A, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418.

[349] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[350] Delio PR, Wong ML, Tsai JP, et al. Assistance from Automated ASPECTS Software Improves Reader Performance (under review 2020).

applicant asserted that the standard deviation of ASPECT scores ranged from 0.35 to 4.5 without assistance as compared to 0.46 to 4.7 with assistance. The applicant stated that the median standard deviation dropped from 2.2 to 1.4 when assistance was used to read the scans. According to the applicant, a t-test to evaluate the hypothesis of equal standard deviations supported a significant difference in standard deviations (p=0.0002), and non-parametric tests arrived at the same conclusion (p <0.0001 for a Wilcoxon Rank Sum Test).[351]

As stated previously, the applicant asserted Rapid ASPECTS represents a substantial clinical improvement by improving treatment decisions and by improving time to treatment. The applicant asserted that in the study performed by iSchemaView of the acute CT scans in patients with LVO (n=50) which were read by eight readers both with and without Rapid ASPECTS, a Receiver Operating Characteristic (ROC) analysis demonstrated significant improvement in typical readers' ability to identify patients who have a score of 6 to 10 if they read the scan in conjunction with the automated score. According to the applicant, the area under the curve (AUC) improved from 0.78 without Rapid ASPECTS to 0.85 with Rapid ASPECTS (p=0.0049). The applicant asserted that of the 400 treatment assessments (50 scans * 8 readers) in this study, 7% were changed from an incorrect assessment to a correct assessment when the scan was read in conjunction with the automated score compared with traditional scoring, a statistically significant difference.[352]

The applicant cited three retrospective studies that, according to the applicant, have shown treatment decisions made by experienced clinicians would have been improved with the use of Rapid ASPECTS.[353] [354] [355] As stated previously, the applicant asserted that one study showed that agreement regarding whether a patient had a treatment-eligible score based on a concurrent MRI scan interpreted by two experts was significantly higher for the Rapid ASPECTS score than for experienced clinicians.[356] According to the applicant, Rapid ASPECTS has also been shown to improve the reads of a typical CT scan reader to become as accurate as a neuroradiologist read.[357] The applicant asserted that since radiologists are not immediately available at the time when many LVO patients present, and obtaining a read from a neuroradiologist often takes even longer, the time to determine an ASPECT score will be substantially improved with the software, leading to faster treatment times which have been shown to reduce disability. According to the applicant, Rapid ASPECTS provides an opportunity to impact the current selection and allocation pathway for stroke care.

After reviewing the information submitted by the applicant, we had the following questions regarding whether Rapid ASPECTS meets the substantial clinical improvement criterion.

In the studies provided by the applicant, the reference ASPECT score to which Rapid ASPECTS was compared was generally derived from a mean value of the ASPECT scores rated from a small sample of expert radiologists. We noted that the radiologists used to identify the reference to which Rapid ASPECTS was compared may not be representative of radiologists in the United States. We were also unclear whether a mean ASPECT score, identified from radiologists whom the applicant describes as having low levels of agreement, is representative of a meaningful value as it does not represent the score of any particular radiologist. We further questioned whether individuals participating in these studies may have altered their behavior in a substantive way by interacting with computer-generated ratings, which would complicate study findings.

We further noted that the correlation between the ASPECT scoring of expert and Rapid ASPECTS is the primary outcome in many of the articles provided. Though this information may be important and informative, we stated it is not clear that a high correlation between expert and Rapid ASPECTS scoring is necessarily indicative of substantial clinical improvement. Furthermore, whether these providers agree with the technology does not determine whether they are correct, and it could be the case that both AI and radiologists agree on an incorrect score.

We noted that the applicant stated that inter-rater disagreement with ASPECT scores leads to erroneous triage and treatment of Medicare patients. We stated it was unclear how the applicant determined that disagreement between scores translates into inappropriate treatment, or necessarily shows that the scoring class (<6 vs ≥6) was inaccurate. The applicant also asserted that many physicians who evaluate acute stroke patients are not confident that they can accurately determine an ASPECT score, but it did not provide evidence to support this claim. Additionally, we observed that the studies provided did not demonstrate improvements in clinical outcomes such as disability, mortality, or length of stay; rather, improved outcomes were inferred by relying on the assumption that faster treatment results in better outcomes. Without measuring the impact of the technology on treatment outcomes, we stated we are uncertain whether Rapid ASPECTS represents a substantial clinical improvement.

Lastly, we noted that the applicant submitted the AHA/ASA guidelines and a review of stroke literature as support for clinical improvement. It is unclear how the guidelines support a finding of substantial clinical improvement for Rapid ASPECTS because the guidelines are for the current standard of care. Additionally, the applicant did not provide evidence to support its assertion that hospitals are not meeting the AHA/ASA guideline that radiologists read the CT scan of acute ischemic stroke patients within 20 minutes. The stroke literature review identified the inter-rater differences among ASPECT scoring, but did not demonstrate that inter-rater disagreements have led to triaging ineligible patients to thrombectomy or failing to treat eligible patients in clinical practice. We stated it is unclear how the literature on inter-rater reliability for ASPECT scoring would demonstrate a substantial clinical improvement in how Rapid ASPECTS supports improved triaging of stroke care. The applicant's stroke literature review also identified that faster treatment leads to better outcomes. While this supports the urgency of stroke care, we were unsure how it demonstrates a substantial clinical improvement in how Rapid ASPECTS supports the urgency of stroke care.

[351] Copeland K. Variability of ASPECT Scores Internal Analysis iSchemaView of data submitted to U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health, 2020a.

[352] Copeland K. Treat/No Treat Analysis, Internal Analysis iSchemaView of data submitted to U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health, 2020.

[353] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[354] Delio PR, Wong ML, Tsai JP, et al. Assistance from Automated ASPECTS Software Improves Reader Performance (under review 2020).

[355] Maegerlein C, Fischer J, Mönch S, MD et al. Automated Calculation of the Alberta Stroke Program Early CT Score: Feasibility and Reliability. *Radiology* 2019; 291:141–148.

[356] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[357] Delio PR, Wong ML, Tsai JP, et al. Assistance from Automated ASPECTS Software Improves Reader Performance (under review 2020).

We invited public comments on whether Rapid ASPECTS meets the substantial clinical improvement criterion.

Comment: The applicant submitted comments in response to CMS' concerns regarding substantial clinical improvement as indicated in the proposed rule. With respect to our concern about sample representation, the applicant stated that two of the studies that were provided, GAMES–RP and Delio et al., used expert readers from the United States.[358] [359] The applicant stated that these two studies included a total of 6 different experts and that the results for Rapid ASPECTS seen in the U.S. studies were similar to the benefits seen in the studies conducted outside of the United States.

With respect to our concern that individuals participating in these studies may have altered their behavior in a substantive way by interacting with computer-generated ratings, the applicant asserted that the expert radiologists who determined the gold standard scores read the cases blinded to the computer-generated ratings, so that there is no possibility that the software influenced these reads. The applicant further stated that the exception to this was the Delio, et al study, where the gold standard was determined independent of the software by three expert neuroradiologists, followed by six ''typical readers'' judging the cases with and without the technology to determine if the assist from Rapid ASPECTS led to reader improvement. The applicant also noted that this study design was endorsed by FDA. Per the applicant, the readers in the first reading session saw the case without Rapid outputs half the time, while during the other half they saw the cases with the Rapid software to assist their read. In a subsequent session, the readers saw the same cases again in reverse: Cases that read without Rapid in the first session were read with Rapid and vice versa. The applicant maintained that the study demonstrated reader improvement with the software assist.

The applicant also commented in response to our concern that the high correlation between the ASPECT scoring of expert and Rapid ASPECTS, which was the primary outcome in many of the articles the applicant provided, demonstrates the accuracy of the technology and is not necessarily indicative of substantial clinical improvement. The applicant maintained that this correlation was not the primary outcome in most studies, citing the example of the GAMES study where the accuracy of the software based on the MRI finding was used as a gold standard.[360] In addition, the applicant cited the Delio, et al and Munich study studies where the gold standard for the primary analysis was the consensus read of multiple experts that was enhanced with the follow-up MRI. The applicant agreed with CMS that both the AI and radiologist could be incorrect, hence why the MRI was used in the GAMES study as the gold standard and in Delio, et al and Munich, the expert radiologists received additional data in the form of a follow-up MRI scan to improve their accuracy. The applicant pointed out that in the prospective study reported by Mansour, et al the door-to-needle time for the standard of care group was 52.3 +/− 16 minutes versus 36.8 +/− 11 minutes (p=0.001) in the Rapid ASPECTS patients which resulted in a 14-minute reduction in the door-to-treatment time. The applicant further noted there was also a significantly increased likelihood of functional independence and fewer hemorrhagic complications in patients treated with reperfusion therapy in the Rapid ASPECTS group (p<0.001).

With respect to our request for more information concerning how inter-rater disagreement with ASPECT scores translates into erroneous triage and treatment of Medicare patients, as well as how inter-rater reliability for ASPECT scoring demonstrates that Rapid ASPECTS supports improved triaging of stroke care, the applicant presented a two-fold argument. The applicant first noted that because appropriate treatment depends on an accurate ASPECT score, Rapid ASPECTS can avoid sending a patient to thrombectomy who has an ASPECT score that does not qualify or failing to treat a patient who does qualify for the procedure. The applicant pointed to the cases cited in its application where one radiologist believed that the score was less than six and the other reader believed that the score was greater than 6. Because only one of these readers can be correct, in these cases the incorrect reader may recommend the wrong treatment decision. By improving the accuracy of the score, the software can avoid these cases of over- or under-treatment. The applicant also pointed to examples of cases where the typical reader's score disagreed with the gold standard score regarding if the patient had a qualifying score of greater than or equal to six, and that in 93 percent of these cases the Rapid ASPECTS score agreed with the gold standard score. Therefore, the applicant argued that a treatment decision based on Rapid ASPECTS would be in line with the more accurate gold standard score and differ from the typical reader's score.

To further bolster their argument, the applicant reiterated that the method for obtaining a ''more accurate'' baseline ASPECT score using the data provided by a follow-up MRI has been accepted by *Radiology, Stroke,* and the *Journal of Stroke and Cerebrovascular Disease* as representing a more accurate score. The applicant pointed out that an MRI scan is much more sensitive than a CT for determining the extent of early brain injury; therefore, the use of a follow-up MRI scan can help increase the accuracy of the baseline ASPECTS read. The applicant acknowledged that while the ASPECTS reader does not have the advantage of knowing what the MRI will eventually show, it is well accepted that having information about the final size of a stroke can make it easier to identify subtle signs of a stroke on the baseline scan. The applicant pointed to the Munich study, GAMES ASPECT study, and Delio et al, which all used a combined baseline CT and follow-up MRI scan as the gold standard and where the Rapid ASPECTS software was demonstrated to be more accurate based on this gold standard than the typical reader.

With respect to our observation that the applicant did not provide evidence to support the claim that many physicians who evaluate acute stroke patients are not confident that they can accurately determine an ASPECT score, the applicant clarified that readers who do not perform well, or read ASPECTS less frequently would have lower confidence, and that the key point is not confidence but rather the accuracy of their scoring. The applicant noted multiple publications showing that non-neuroradiologists and less experienced readers are less accurate than experienced neuroradiologists when performing ASPECTS scoring, such as the Delio et al study where the scores of the neurologists and ER physician were considerably less accurate than the two neuroradiologists.[361] In this same study, the scores of the neurologists and ER physician were as accurate as the two neuroradiologists during a Rapid

[358] Delio PR, Wong ML, Tsai JP, et al. Assistance from Automated ASPECTS Software Improves Reader Performance (under review 2020).

[359] Sheth KN, Elm JJ, Beslow LA, Sze GK, Kimberly WT, et al. Glyburide Advantage in Malignant Edema and Stroke (GAMES–RP) Trial: Rationale and design. *Neurocrit Care.* 2016; 24: 132–139.

[360] Id.

[361] Delio PR, Wong ML, Tsai JP, et al. Assistance from Automated ASPECTS Software Improves Reader Performance (under review 2020).

ASPECTS assisted read and using the gold standard score as the reference. The applicant referred CMS to two additional studies, where a better correlation between the expert consensus and the readers was documented for more experienced readers compared with less experienced readers.[362] [363]

With respect to our concern that the studies provided did not demonstrate improvements in clinical outcomes such as disability, mortality, and length of stay, the applicant again pointed to the prospective study reported by Mansour, et al where the door-to-needle time for the standard care group was 52.3 +/− 16 minutes vs. 36.8 +/− 11 minutes (p=0.001) in the Rapid ASPECTS patients which resulted in a 14-minute reduction in the door-to-treatment time. The applicant reiterated that there was also a significantly increased likelihood of functional independence and fewer hemorrhagic complications in patients treated with reperfusion therapy in the Rapid ASPECTS group ($p < 0.001$). The applicant then presented new data from the United States showing that time to treatment with thrombectomy was reduced following introduction of Rapid ASPECTS. Per the applicant, the study was performed at two comprehensive centers and one primary stroke center and observed a substantial reduction of approximately 35 minutes in the time from ER arrival to when the MDs were provided with an assessment of the non-contrast CT scan results for patients with suspected stroke. During the SOC phase of the study (pre-ASPECTS) the median time for the radiology read to be performed was 46 minutes vs 9.5 minutes for the treating MDs to receive the Rapid ASPECTS report in the post-ASPECTS phase. Furthermore, the radiologists were able to read the CT scan 6 minutes faster when they had the Rapid interpretation available. In addition, although only a limited number of patients received thrombectomy during the study period, there were compelling trends toward lower mortality and a higher rate of functional recovery at 90 days in the post-ASPECTS phase. Per the applicant, these data demonstrate that the Rapid ASPECTS software provides diagnostic data on suspected stroke patients considerably faster than SOC and provides evidence that earlier access to this diagnostic data improves stroke outcomes.

With respect to our request for clarity on how the AHA/ASA guidelines for the current standard of care support a finding of substantial clinical improvement for Rapid ASPECTS, the applicant stated that these guidelines require an ASPECT score of 6 or higher for the patient to receive thrombectomy in the 6-hour treatment window, and that they therefore assume that an accurate ASPECT score can be calculated and used to make an appropriate treatment decision. The applicant stated that the accuracy of the ASPECT score can be improved with the Rapid ASPECTS software, especially for less experienced readers, and that in addition there is clear evidence that the ASPECTS score can be generated more quickly with the assistance of the software, especially in hospitals that do not have immediate access to expert neuroradiologists. Regarding the lack of evidence to support the assertion that hospitals are not meeting the AHA/ASA guideline that radiologists read the CT of acute ischemic stroke patients within 20 minutes, the applicant pointed out that current Medicare guidelines state that the radiologist interpretation of the scan should occur within 45 minutes of arrival, and that they included Medicare data indicated that only 72 percent of patients meet these guidelines.

The applicant commented in response to CMS' numerous concerns regarding the relevance of the stroke literature review provided in its application. Regarding the literature on inter-rater reliability for ASPECT scoring and how it demonstrates a substantial clinical improvement in how Rapid ASPECTS supports improved triaging of stroke care, the applicant pointed to the three retrospective studies showing that an incorrect ASPECT score was chosen by a typical clinical reader approximately seven percent of the time based on the gold standard determined in each study, and that this leads to either an unnecessary procedure or an eligible patient not being treated with thrombectomy. The applicant emphasized that unnecessary procedures are costly and that thrombectomy is associated with a small risk of serious complications. The applicant stated that patients who are not treated with thrombectomy because the ASPECTS score is erroneously low will miss out on the substantial benefits of thrombectomy which include shorter length of stay, faster recovery time, improvement in activities of daily living, and improved quality of life. Regarding our uncertainty over how the applicant's literature review, which supports the urgency of stroke care, also demonstrates a substantial clinical improvement in how Rapid ASPECTS supports the urgency of stroke care, the applicant maintained that Rapid ASPECTS is highly likely to provide diagnostic information to treating physicians much faster than the current standard of care. Per the applicant, the Rapid ASPECTS score is generated and made available to treating physicians within two and a half minutes after the CT scan is completed whereas current AHA guidelines recommend that a radiologist reads the CT scan within 20 minutes, a metric that is often not met. The applicant pointed to a recent study from Johns Hopkins where use of the Rapid mobile app (app) for detection of large vessel occlusion (data presented to MDs about 2.5 minutes after the scan is completed) resulted in a 33 min reduction in door to groin thrombectomy times (P=0.02), and 37 min reduction in door to recanalization time (P=0.02) when compared with patients treated pre-app. The applicant also noted that the National Institutes of Health Stroke Scale (NIHSS) 24 hours after procedure and at discharge were significantly lower in the post-app group (P=0.03).[364] The applicant pointed to the new data that they cited in response to our concern that the studies provided did not demonstrate improvements in clinical outcomes, which show that time to treatment with thrombectomy was reduced following introduction of Rapid ASPECTS; specifically, that there was a 35-minute reduction in the time from ER arrival to when the MDs were provided with an assessment of the non-contrast CT scan results for patients with suspected stroke, the radiologists were able to read the CT scan 6 minutes faster when they had the Rapid interpretation available, and although only a limited number of patients received thrombectomy during the study period, the applicant observed compelling trends toward lower mortality and a higher rate of functional recovery at 90 days in the post-ASPECTS phase.

The applicant then commented in response to our concerns regarding the additional data submitted in response to questions received at the New Technology Town Hall Meeting held in December 2020. With respect to our concerns about the generalizability of Mansour et al, given the small, non-

[362] Kobkitsuksakul C, Tritanon O, Suraratdecha V. Interobserver agreement between senior radiology resident, neuroradiology fellow, and experienced neuroradiologist in the rating of Alberta Stroke Program Early Computed Tomography Score (ASPECTS). Diagn Interv Radiol. 2018.

[363] Culbertson CJ, Christensen S, Mlynash M, et al. Tilt-Corrected Region Boundaries May Enhance the Alberta Stroke Program Early Computed Tomography Score for Less Experienced Raters. J Stroke Cerebrovasc Dis. 2020 Jul;29(7):104820.

[364] Al-Kawaz M, Primiani C, Urrutia V, Hui F. Impact of RapidAI mobile application on treatment times in patients with large vessel occlusion. J NeuroIntervent Surg 2021;0:1–4.

randomized sample generated from a single hospital in Egypt, the applicant acknowledged that there are indeed limitations to the study, and that it occurred outside of the United States. With respect to our concern regarding one patient in the retrospective study for whom the Rapid ASPECTS-generated score and agreement read differed, suggesting that the tPA treatment the patient received was not appropriate, the applicant noted that an ASPECTS score of less than six is a contraindication to thrombectomy but is not a contraindication to tPA. The applicant provided new data from the United States to supplement this data, which show that time to treatment with thrombectomy was reduced following introduction of Rapid ASPECTS. The applicant also provided the Johns Hopkins study summarized previously showing treatment times and improved outcomes.

Other commenters cited their clinical experience using Rapid ASPECTS and echoed the applicant's comments regarding the importance of early intervention in stroke care. These commenters stated that, for patients with acute ischemic stroke with large vessel occlusions, these benefits from mechanical thrombectomy are time dependent. The commenters expressed their support of new technology add-on payments for Rapid ASPECTS, stating that incorporating technologies such as Rapid ASPECTS reduces the time to interpret the imaging studies needed to make treatment decisions, thus saving lives and reducing disability.

Response: We appreciate the commenters' input and the additional data from the applicant to address our concerns. However, after review of all the data received to date, we continue to have concerns related to the substantial clinical improvement criterion as noted in the FY 2022 IPPS/LTCH PPS proposed rule. Specifically, it remains unclear whether the use of Rapid ASPECTS significantly improves clinical outcomes for PE patients as compared to currently available treatments as the applicant did not measure the impact of the technology on outcome measures such as mortality, length of stay, and disability. This is in contrast to the data presented in response to CMS' concerns regarding Viz.ai's ContaCT, which demonstrated not only reduced time to notification but also an improved 5-day NIH Stroke Score (NIHSS) and lower Modified Rankin Score (mRS) post-ContaCT implementation among patients presenting to a primary stroke system who subsequently underwent mechanical thrombectomy. While the applicant has demonstrated that Rapid ASPECTS reduces time to notification, it has not shown that improved outcomes resulting from faster treatment are necessarily due to Rapid ASPECTS, as there are many variables in the hospital workflow that may influence management of the patient and time savings. We note that the Johns Hopkins study did not evaluate Rapid ASPECTS but rather the Rapid Mobile App for the detection of LVO. We also note that current Medicare guidelines, which state that the radiologist interpretation of the scan should occur within 45 minutes of arrival, do not apply to Rapid ASPECTS. The guidelines state that the CT should be read within 45 minutes of arrival in order to diagnose a stroke whereas Rapid ASPECTS is indicated for use in stroke patients only after the diagnosis has been made.

Therefore, after consideration of the public comments we received and based on the information stated previously, we are unable to determine that Rapid ASPECTS represents a substantial clinical improvement over existing technologies, and we are not approving new technology add-on payments for Rapid ASPECTS for FY 2022.

l. Steripath® Micro™ Blood Collection System

Magnolia Medical Technologies, Inc. submitted an application for new technology add-on payments for the Steripath® Micro™ Blood Collection System, which is also referred to as the Steripath® Micro™ Initial Specimen Diversion Device (ISDD®), for FY 2022. The applicant described the Steripath® Micro™ ISDD® (''Steripath Micro'') as a proprietary and patent-protected single-use, disposable device, which is indicated for use in the collection of blood cultures by nurses, phlebotomists, and technicians in emergency departments and inpatient units in acute care hospitals to reduce blood culture contamination and false positive diagnostic test results for sepsis. According to the applicant, Steripath® Micro™ ISDD®, along with the Steripath and Steripath® Gen2, are part of a product portfolio utilizing their Steripath® ISSD® technology.

The applicant explained that the Steripath® Micro™ ISDD® uses a syringe-driven (or blood culture bottle-driven) architecture that uses negative pressure to flip a proprietary internal bladder, which, in turn, creates gentle negative pressure to divert and sequester the initial 0.6 to 0.9 mL of blood, the portion known to most likely contain contaminants. According to the applicant, once diversion is complete, the user presses a side button to isolate the diverted blood. The applicant further explained that once the blood is isolated, a second independent blood flow pathway is opened to collect the blood specimen into the syringe (or blood culture bottle) for blood culture testing.

The applicant stated that the design and development of the Steripath® Micro™ ISDD® was inspired by patients who present with symptoms concerning for sepsis and who are hypotensive (low blood pressure) and hypovolemic (low blood volume), have difficult intravenous access (DIVA), or are small in stature with lower blood volume. According to the applicant, clinicians typically utilize a syringe technique to collect blood from this patient population to enable management of negative pressure (attempting to avoid vein collapse) while improving the opportunity to collect a sufficient volume of blood to culture, which the applicant stated is a critical determinant of blood culture sensitivity (that is, avoiding false negative results). The applicant claimed that this patient population is generally ineligible for existing ISDD® technologies due to risk of vein collapse. According to the applicant, the negative pressure created by Steripath® Micro™ ISDD®'s bladder-driven mechanism is designed to achieve initial specimen diversion while avoiding collapsing of the veins (losing venous access) of this patient population. The applicant stated that the Steripath® Micro™ ISDD® is available with a preassembled sterile integrated syringe for syringe-driven diversion and blood culture sample collection, and components of the system may be used for infusion following sample collection after disconnection of the ISDD®.

According to the applicant, blood culture is the gold standard diagnostic test for bloodstream infections, including septicemia. The applicant explained that blood cultures are drawn from patients displaying symptoms of a potential bloodstream infection with results guiding therapeutic decisions and influencing outcomes for patients for their duration in acute care. The applicant stated that the standard of care is to collect two separate blood cultures, each consisting of two blood culture bottles containing aerobic or anaerobic medium. The applicant further noted that the major automated microbial blood culture detection systems (BACTEC and BacT/ALERT) recommend 8–10 mL of blood in each of the aerobic and anaerobic bottles—up to 40 mL total distributed across all four bottles.

The applicant stated that despite the critical role blood culture plays in providing diagnoses, an estimated 20 percent to over 50 percent of all positive blood culture results for sepsis are suspected to be false positive due to blood culture contamination, as explained in greater detail below.[365] The applicant stated that blood culture contamination creates clinical confusion which leads to a risk of inappropriate antibiotic therapy,[366] [367] [368] [369] extended length of stay of an average of 2.0 to 2.4 days,[370] [371] *Clostridium difficile* (CDI) infection,[372] [373] multidrug resistance organism (MDRO) infections, Acute Kidney Injury (AKI),[374] hospital-acquired infection (HAI) or hospital-acquired condition (HAC),[375] false-positive Central Line-Associated Blood Stream Infection (CLABSI) treatment, false positives reported to National Healthcare Safety Network (NHSN)/CMS (thus biasing the data), and additional lab and/or other diagnostic testing.[376]

The applicant explained that the detection of bacteremia is of particular concern for Medicare beneficiaries, given that the mean age for United States patients afflicted with sepsis in 2014 was 66.5, with sepsis present in 35 percent of all United States hospitalizations that resulted in death.[377]

With regard to the newness criterion, the Steripath® Micro™ ISDD® is a Class II medical device that received 510(k) clearance from the FDA on October 8, 2020. The 510(k) clearance was based on substantial equivalence to an earlier version of the device, Steripath® Gen2, which received 510(k) clearance on February 28, 2020. According to the applicant, the Steripath® ISDD® product portfolio, including the Steripath® Micro™ ISDD®, is the only FDA 510(k)-cleared family of devices indicated to reduce blood culture contamination.[378] According to the applicant, a supplemental Special 510(k) submission and clearance is anticipated for an additional configuration of the Steripath® Micro™ ISDD® device that incorporates a butterfly safety venipuncture needle.

The applicant submitted a request for a new ICD–10–PCS procedure code and was granted approval for the following procedure code effective October 1, 2021: XXE5XR7 (Measurement of infection, mechanical initial specimen diversion technique using active negative pressure, new technology group 7).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

According to the applicant, diversion techniques use the same basic principle to reduce blood culture contamination by sequestering blood most likely to contain dislodged skin fragments and/or flora. With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant discussed current/alternative treatments to avoid blood contamination, but states that manual diversion, passive diversion, and the Steripath® Gen2 device are not comparable alternatives to Steripath® Micro™.

According to the applicant, manual diversion, which involves the phlebotomist or other medical professional first collecting blood into a waste tube and then manually switching to a sample collection tube, is not a replacement for Steripath® Micro™ ISDD® because manual diversion inherently entails additional opportunities for human error through touch contamination and process variation, without the ability to manage and ensure healthcare worker compliance. The applicant further explained that manual diversion techniques introduce, at a minimum, one additional surface (waste tube top), which must either be sterilized (or carefully handled if pre-packaged sterile) to avoid cross contamination through the inoculation needle. The applicant noted that if the inoculation needle is contaminated in this manner, both blood culture bottles can become contaminated, which can be interpreted (inaccurately) as a true positive through laboratory testing. The applicant explained that Steripath® Micro™ ISDD® is a closed system to prevent opportunities for touch contamination beyond conventional methods of blood culture sample acquisition. The applicant further explained that since Steripath® Micro™ ISDD® is a pre-assembled and packaged sterile kit that does not require manual connections, it avoids touch-point contamination and prevents the need for additional time, focus, and manual diversion procedural compliance from the operator.

The applicant stated that the Kurin product, a competitor diversion device that uses passive diversion (or relying on the patient's blood pressure), is not a comparable alternative to Steripath® Micro™ ISDD® as it is not FDA-cleared to reduce blood-culture contamination. The applicant claimed that passive diversion, because of its limitations, is integrated into the Kurin product to redirect 0.15 mL of blood. The applicant stated that passive devices are susceptible to bypassing diversion when the culture bottle is inoculated before diversion is complete, and that this limitation is not present within the Steripath® Micro™ ISDD® architecture. The applicant asserted that the Steripath® Micro™ ISDD® uses a novel syringe-driven (or blood culture bottle-driven) negative pressure to flip an internal bladder which, in turn, creates gentle negative pressure to divert and

[365] Snyder S, et al. Effectiveness of practices to reduce blood culture contamination: A Laboratory Medicine Best Practices systematic review and meta-analysis. *Clinical Biochemistry.* 2012; 45(0):999–1011.

[366] Rupp M, et al. Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device. *Clinical Infectious Diseases.* 2017; 65(2):201–205.

[367] Bell M, et al. Effectiveness of a novel specimen collection system in reducing blood culture contamination rates. Journal of Emergency Nursing 44.6 (2018): 570–575.

[368] Doern G, et al. A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem. Clinical Microbiology Reviews. 2020; 33:e00009–19.

[369] Chang D, et al. Impact of blood culture diversion device on molecular pathogen identification on vancomycin use. Poster presented at: Society for Healthcare Epidemiology of America (2017).

[370] Skoglund E et al. Estimated Clinical and Economic Impact through Use of a Novel Blood Collection Device To Reduce Blood Culture Contamination in the Emergency Department: A Cost-Benefit Analysis. 2019; 57:e01015–18.

[371] Geisler B, et al. Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures oneconomic and clinical outcomes. *Journal of Hospital Infection.* 2019; 102:438–444.

[372] Ibid. Geisler B, et al. Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures oneconomic and clinical outcomes. *Journal of Hospital Infection.* 2019; 102:438–444.

[373] Doern G, et al. A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem. Clinical Microbiology Reviews. 2020; 33:e00009–19.

[374] Khalili H, et al. ''Antibiotics induced acute kidney injury: Incidence, risk factors, onset time and outcome.'' Acta Medica Iranica (2013): 51(12): 871–878.

[375] Doern G, et al. A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem. *Clinical Microbiology Reviews.* 2020; 33:e00009–19.

[376] Ibid. Doern G, et al. A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem. *Clinical Microbiology Reviews.* 2020; 33:e00009–19.

[377] Rhee C, et al. Incidence and Trends of Sepsis in US Hospitals Using Clinical vs Claims Data, 2009–2014. *JAMA.* 2017; 318:1241–1249.

[378] Bell, Mary, et al. Effectiveness of a novel specimen collection system in reducing blood culture contamination rates. *Journal of Emergency Nursing* 44.6 (2018): 570–575.

sequester the initial 0.6 to 0.9 mL of blood.

The applicant further stated that the Steripath® Gen2 ISDD® is not a comparable product to Steripath® Micro™ ISDD®, as it uses greater negative pressure to divert an initial 1.5–2.0 mL of blood for the adult patient population. According to the applicant, the Steripath® Micro™ ISDD® platform leverages ISDD® technology but is smaller, easier-to-use, and employs a novel proprietary diversion bladder technology to address patients who are hypotensive and hypovolemic, have difficult intravenous access, or are small in stature with lower blood volume. Specifically, the applicant explained that the Steripath® Micro™ ISDD® uses syringe-driven (or blood culture bottle-driven) negative pressure to flip an internal bladder which in turn creates gentle negative pressure to effectively and consistently divert and sequester the initial 0.6 to 0.9 mL of blood, the portion known to most likely contain contaminants, with this patient population. The applicant asserts this differentiates the Steripath® Micro™ from the Steripath® Gen2. The applicant further explained that once diversion is complete, the user presses a button to isolate the diverted blood and, automatically, a second independent blood flow pathway opens to collect the blood specimen into the syringe (or blood culture bottle) for culture.

With respect to the second criterion, whether the technology is assigned to the same or a different MS–DRG, the applicant did not indicate whether the Steripath® Micro™ ISDD® would be assigned to the same MS–DRGs as cases representing patients who receive diagnostic information from competing technologies or traditional blood collection methods.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that the Steripath® Micro™ ISDD® was fundamentally designed to address a specific and broader patient population than any other technology that is currently available and FDA 510(k) cleared to prevent blood culture contamination. The applicant explained that in a certain subset of 'hard-stick' (low blood volume, hypovolemic and hypotensive) patients, blood culture using passive diversion or the Steripath® Gen2 ISDD® is not possible. According to the applicant, Steripath® Micro™ is the first ISDD designed specifically to address the unmet needs of the low blood volume, hypovolemic and hypotensive, 'hard-stick' patient populations (many requiring integrated sterile syringe collection) that is FDA 510(k) cleared indicated to reduce blood culture contamination.

In the proposed rule (86 FR 25316), we noted the following concerns regarding whether the technology meets the substantial similarity criteria and whether it should be considered new. Although we understand that the Steripath® Micro™ ISDD® version may divert less blood volume and utilize less negative pressure than the Steripath® Gen2 ISDD®, we noted that both devices utilize negative pressure and, according to the applicant, leveraged Magnolia Medical Technologies' foundational ISDD® technology, and it is unclear whether this represents a new mechanism of action. We further noted that the applicant also appears to consider the devices as similar, as they exclusively rely on studies conducted using the Steripath® Gen2 ISDD® to demonstrate substantial clinical improvement. We stated that we believe that the newness date for Steripath® Micro™ ISDD® would begin on February 28, 2020, the date on which the predicate device received 510(k) clearance. We also noted that the applicant claimed that the Steripath® ISDD® product portfolio, including the Steripath® Micro™ ISDD®, is the only FDA 510(k)-cleared family of devices indicated to reduce blood culture contamination and we invited public comment on whether there are other FDA-cleared products designed to reduce blood culture contamination.

We invited public comments on whether the Steripath® Micro™ ISDD® is substantially similar to other technologies and whether the Steripath® Micro™ ISDD® meets the newness criterion.

Comment: The applicant submitted a letter asserting that Steripath® Micro™ ISDD® meets the newness criterion. In response to our concern regarding whether the Steripath® Micro™ ISDD® difference constituted a new mechanism of action, the applicant stated that the reduced diversion volume, the lower average peak negative pressure of Steripath® Micro™ ISDD® compared to Steripath® Gen2 ISDD®, and the pre-assembled integrated syringe configuration allowing for precise end-user control of the negative pressure constitute a new mechanism of action. The applicant stated that these features allow the Steripath® Micro™ ISDD® to offer the same clinical benefits of the Steripath® Gen2 ISDD® to the DIVA, hypovolemic, hypotensive, and small-in-stature populations. The applicant also stated that initial feedback from commercial users of the Steripath® Micro™ ISDD® is overwhelmingly positive, noting ease of use and utility for patients with fragile veins and vasculature. The applicant stated that clinical use data and end-user feedback to date shows that the novel mechanism of action is meeting the needs of the previously unserved DIVA population; however, the applicant did not provide data to support this claim. The applicant also stated that Steripath® Micro™ ISDD® enables an equitable standard of care for sepsis testing accuracy and prevention of misdiagnosis for an expanded Medicare-eligible patient population.

In response to our concern regarding the applicant's reliance of on clinical data from the Steripath® Gen2 ISDD® indicating that the two devices may be substantially similar, the applicant stated that reliance on a predicate device's supporting clinical literature is not one of the newness criteria. The applicant stated that the unique mechanism of action of Steripath® Micro™ ISDD® and the new target population differentiate the two devices. The Steripath® Micro™ ISDD® was FDA cleared on October 8, 2020. The applicant stated, however, that the commercial launch date was March 31, 2021, and should function as the newness date.

A few commenters stated that the Steripath® Micro™ ISDD® is needed for the DIVA population. These commenters generally noted the efficacy of the Steripath® Gen2 ISDD®, but stated that it may not be appropriate for use in the DIVA population, and welcome the arrival of the Steripath® Micro™ ISDD®.

Response: We thank the commenters for their perspective on the mechanism of action and potential benefits of Steripath® Micro™ ISDD® to the DIVA population and have taken them under into consideration. We also appreciate the information provided by the applicant regarding the newness criterion. However, after consideration of the information provided, we continue to believe that the mechanism of action is substantially similar to that of its predicate device, Steripath® Gen2 ISDD®. While the applicant provides information that differentiates the Steripath® Micro™ ISDD® from the Steripath® Gen2 ISDD®, we do not believe that these differences rise to the level of a new mechanism of action. We believe that the differences of reduced diversion volume, lower average peak negative pressure, and the pre-assembled integrated syringe configuration allowing for precise end-user control of the negative pressure are iterative updates. The two devices still

work using the same mechanism of action, which is sequestration of the initial flash of blood during blood collection to remove skin flora and or other contaminants. We also continue to believe that the DIVA population may already be served by the Steripath® Gen2 product since the Magnolia Medical Steripath® Gen2 website states so directly.[379] [380] Lastly, we believe cases involving Steripath® Micro™ ISDD® would be assigned to the same MS–DRGs as cases involving Steripath® Gen2 ISDD®.

After consideration of all the information from the applicant, as well as the comments we received, we believe that the Steripath® Micro™ ISDD® is substantially similar to the Steripath Gen2 ISDD®. Since the Steripath® Gen2 received marketing authorization on February 28, 2020, we therefore consider the newness date for the Steripath Micro™ ISDD® to begin on February 28, 2020.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR FR claims data file with the FY 2019 Final Rule IPPS Impact File to identify potential cases representing patients who may be eligible for treatment using Steripath® Micro™ ISDD®.

The applicant used 37 Infection ICD–10–CM Diagnosis Codes and 15 Sepsis ICD–10–CM Diagnosis codes to identify patients who could potentially benefit from the Steripath® Micro™ ISDD® during an inpatient stay. These ICD–10–CM codes are provided in the following table:

BILLING CODE 4120–01–P

	37 Infection ICD-10-CM Diagnosis Codes
Code	**Code Descriptor**
A04.0	Enteropathogenic Escherichia coli infection
A04.1	Enterotoxigenic Escherichia coli infection
A04.2	Enteroinvasive Escherichia coli infection
A04.3	Enterohemorrhagic Escherichia coli infection
A04.4	Other intestinal Escherichia coli infections
A24.9	Melioidosis, unspecified
A49.01	Methicillin susceptible Staphylococcus aureus infection, unspecified site
A49.02	Methicillin resistant Staphylococcus aureus infection, unspecified site
A49.9	Bacterial infection, unspecified
B95.2	Enterococcus as the cause of diseases classified elsewhere
B95.61	Methicillin susceptible Staphylococcus aureus infection as the cause of diseases classified elsewhere
B95.62	Methicillin resistant Staphylococcus aureus infection as the cause of diseases classified elsewhere
B95.7	Other staphylococcus as the cause of diseases classified elsewhere
B96.1	Klebsiella pneumoniae [K. pneumoniae] as the cause of diseases classified elsewhere
B96.20	Unspecified Escherichia coli [E. coli] as the cause of diseases classified elsewhere
B96.21	Shiga toxin-producing Escherichia coli [E. coli] (STEC) O157 as the cause of diseases classified elsewhere
B96.22	Other specified Shiga toxin-producing Escherichia coli [E. coli] (STEC) as the cause of diseases classified elsewhere
B96.29	Other Escherichia coli [E. coli] as the cause of diseases classified elsewhere
B96.5	Pseudomonas (aeruginosa) (mallei) (pseudomallei) as the cause of diseases classified elsewhere
J15.0	Pneumonia due to Klebsiella pneumoniae
J15.1	Pneumonia due to Pseudomonas
J15.20	Pneumonia due to staphylococcus, unspecified
J15.211	Pneumonia due to Methicillin susceptible Staphylococcus aureus
J15.212	Pneumonia due to Methicillin resistant Staphylococcus aureus
J15.5	Pneumonia due to Escherichia coli
J15.6	Pneumonia due to other Gram-negative bacteria
J95.851	Ventilator associated pneumonia
K55.30	Necrotizing enterocolitis, unspecified
K55.31	Stage 1 necrotizing enterocolitis
K55.32	Stage 2 necrotizing enterocolitis
K55.33	Stage 3 necrotizing enterocolitis
N39.0	Urinary tract infection, site not specified
R78.81	Bacteremia
T81.4XXA	Infection following a procedure, initial encounter
Z22.321	Carrier or suspected carrier of Methicillin susceptible Staphylococcus aureus
Z22.322	Carrier or suspected carrier of Methicillin resistant Staphylococcus aureus
Z86.14	Personal history of Methicillin resistant Staphylococcus aureus infection

[379] Magnolia Medical Launches New Steripath Gen2 with Integrated Syringe. Magnolia Medical Technologies. (July 8, 2020) *https://magnolia-medical.com/press-releases/steripath-gen2-with-integrated-syringe/.*

[380] Steripath® Gen2 Initial Specimen Diversion Device. Magnolia Medical Technologies. (n.d.) *https://magnolia-medical.com/steripath/gen2/.*

	15 Sepsis ICD-10-CM Diagnosis codes
Code	**Code Descriptor**
A26.7	Erysipelothrix sepsis
A32.7	Listerial sepsis
A41.01	Sepsis due to Methicillin susceptible Staphylococcus aureus
A41.02	Sepsis due to Methicillin resistant Staphylococcus aureus
A41.1	Sepsis due to other specified staphylococcus
A41.2	Sepsis due to unspecified staphylococcus
A41.50	Gram-negative sepsis, unspecified
A41.51	Sepsis due to Escherichia coli [E. coli]
A41.52	Sepsis due to Pseudomonas
A41.59	Other Gram-negative sepsis
A41.81	Sepsis due to Enterococcus
A41.89	Other specified sepsis

	15 Sepsis ICD-10-CM Diagnosis codes
Code	**Code Descriptor**
A41.9	Sepsis, unspecified organism
R65.20	Severe sepsis without septic shock
R65.21	Severe sepsis with septic shock

BILLING CODE 4120–01–C

In its analysis, the applicant identified a primary cohort to assess whether this therapy met the cost criterion. The applicant stated that clinical literature suggests the DIVA population represents anywhere from 17 percent to 59 percent of all patients that present as symptomatic for sepsis and require blood cultures.[381] [382] [383] The applicant added that the literature did not provide any additional information on the distribution of the DIVA population within the larger infection/sepsis population. To account for this, the applicant randomly selected 33% of claims that included one of the ICD–10 codes listed previously in one of the first two diagnosis code positions on the claim to include in the cost analysis.

The applicant removed MS–DRGs describing kidney and urinary tract infections and renal failure because these cases are not likely to benefit from use of the Steripath® Micro™ ISDD®. The applicant stated that these diagnoses rely on technologies not relevant to Steripath® Micro™ ISDD®, such as urine cultures and blood cultures specific to urea and creatinine. Lastly the applicant excluded cases in MS–DRGs that accounted for less than 1% of the total cases in the identified sample.

The claim search conducted by the applicant resulted in 295,790 claims mapping to six MS–DRGs: 871 (Septicemia or severe sepsis w/o mv >96 hours w mcc), 872 (Septicemia or severe sepsis w/o mv >96 hours w/o mcc), 853 (Infectious & parasitic diseases w O.R. procedure w mcc), 870 (Septicemia or severe sepsis w mv >96 hours or peripheral extracorporeal membrane oxygenation (ECMO)), 854 (Infectious & parasitic diseases w O.R. procedure w cc), and 177 (Respiratory infections & inflammations w mcc). The applicant determined an average unstandardized case weighted charge per case of $69,973.

The applicant stated that studies show blood culture contamination (BCC) increases length of stay (LOS) and leads to unnecessary antimicrobial therapy and/or hospital-acquired conditions. The applicant stated that a retrospective analysis involving hospitalized patients with septicemia-compatible symptoms found that avoiding BCC would decrease costs by $6,463, including $4,818 in savings for inpatient care. 53 percent of savings were attributed to reduced LOS and 26 percent to reduced antibiotic use.[384] The applicant stated that to account for these savings, they removed $2,500 by inflating costs to charges using the national average cost-to-charge ratio (CCR) for routine days and $2,300 by inflating costs to charges using the pharmacy national average CCR. Because the previous study cited did not describe where non-LOS related inpatient savings arose, the applicant assumed that the savings arose from reduced drug use and therefore the pharmacy national average CCR was used.

Because, according to the applicant, savings accrue in around 3% of cases where the Steripath® Micro™ ISDD® is used, the applicant applied three percent of the savings described previously to every case in the sample population. The applicant stated that removing the $4,800 in cost savings from 3 percent of the cases is mathematically the same as removing 3 percent of the cost savings from all cases. The applicant then standardized the charges using the FY 2019 Final Rule Impact File. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the technology, the applicant used the national average CCR for the Supplies and Equipment cost center of 0.297 from the FY 2021 Final IPPS rule. The applicant calculated a final inflated

[381] Sou, V., et al. A clinical pathway for the management of difficult venous access. BMC Nursing 16, 64 (2017).

[382] Armenteros-Yeguas V., et al. Prevalence of difficult venous access and associated risk factors in highly complex hospitalized patients. J Clin Nurs. 2017;26(23–24):4267–4275.

[383] Van Loon, FH, et al. Development of the A–DIVA Scale: A Clinical Predictive Scale to Identify Difficult Intravenous Access in Adult Patients Based on Clinical Observations. Medicine. 2016 Apr;95(16)e3428.

[384] Geisler, BP, *et al.* Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures on economical and clinical outcomes. J Hosp Infect. 2019 Aug;102(4):438–444.

average case-weighted standardized charge per case of $76,796, which exceeded the average case-weighted threshold amount of $69,973 by $6,824. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

Based on the information provided by the applicant, we noted the following concerns with regard to the cost criterion in the proposed rule. In its analysis, the applicant stated it randomly selected 33% of claims that included one of the ICD–10 codes listed previously in one of the first two diagnosis code positions on the claim to include in the cost analysis. Implicit in this decision to randomly select a subsample is the belief that Steripath® Micro™ ISDD® cases are randomly distributed across all cases identified. If performed properly, the intent of random sampling from a population is to identify a smaller group of cases which remains representative or similar to the greater population. An added effect of proper random sampling is that the sample often has less variance than the population from which it was drawn. We stated that we are therefore concerned that random sampling may be inappropriate in this situation if the potential cases are not similarly randomly distributed. Furthermore, if it is true that a subset of cases would be more representive of cases eligible for use of the Steripath® Micro™ ISDD®, it may be more likely that those cases will be distributed based on certain characteristics, not randomly distributed. We sought public comment on whether the random sample used by the applicant would appropriately identify the cases eligible for the use of Steripath.

In its cost analysis, the applicant stated that, in order to account for savings from the use of Steripath® Micro™ ISDD®, it removed $2,500 by inflating costs to charges using the national average cost-to-charge ratio (CCR) for routine days and $2,300 by inflating costs to charges using the pharmacy national average CCR. We stated in the proposed rule that from a methodological standpoint, we are not certain that the data from which savings were calculated are generalizable to the broader Medicare population's experience if Steripath® Micro™ Blood Collection System is used. Specifically, we were not certain that the patient population and the resulting conclusions from the aforementioned study [385] adequately generalize to the Medicare population.

Lastly, the applicant stated that because savings accrue in around three percent of cases where the Steripath® Micro™ ISDD® is used, the applicant applied three percent of the savings described previously to every case in its sample population. We stated we were unclear whether the three percent of cases which experienced savings in the one study provided by the applicant is adequately representative of the Medicare population. We were not certain that three percent of a sample experiencing some level of savings is the same as all cases experiencing three percent savings. Therefore, we were not certain that it is appropriate to apply three percent of savings across all cases in the applicant's cost analysis. As with the reduction in charges discussed previously, while the applicant's approach provides a more conservative estimate for purposes of the cost criterion, we questioned whether it accurately reflects the experiences of providers and Medicare beneficiaries.

We invited public comment on whether Steripath® Micro™ ISDD® meets the cost criterion.

Comment: A commenter, the applicant, submitted comments in response to our concerns on whether Steripath® Micro™ ISDD® meets the cost criterion. With respect to our concern regarding the random sampling used by the applicant and whether it appropriately identified the cases eligible for the use of Steripath® Micro™ ISDD®, the applicant pointed to clinical literature suggesting that the DIVA population represents approximately 17 to 59 percent of all patients that present symptomatic for sepsis and require blood cultures. The applicant further explained that it did not have evidence that patients who are eligible for Steripath® Micro™ ISDD® would match any particular profile that could be identified through claims data. For instance, the applicant did not have any evidence to suggest that patients in the DIVA population have more or less costly inpatient stays. Accordingly, in its original analysis, the applicant randomly selected 33 percent of claims from its full sample that included one of the ICD–10 codes listed in its application in one of the first two diagnosis code positions. The applicant acknowledged that selecting claims is an imperfect process that requires assumptions to be made in the absence of clear selection criteria, and in response to CMS' concern reran its analysis using the full sample cases, which resulted in a final inflated case-weighted standardized charge per case that exceeded the case weighted threshold. Thus, the applicant maintained that Steripath® Micro™ ISDD® meets the cost criterion.

With respect to our concern that the savings calculated may not be generalizable to the broader Medicare population, the applicant pointed to a retrospective analysis involving hospitalized patients with septicemia-compatible symptoms. The applicant stated that this analysis found that avoiding blood culture contamination would decrease costs by $6,463, including $4,818 in savings for inpatient care, 53 percent of which were attributed to reduced length of stay and 26 percent to reduced antibiotic use. The applicant removed $2,500 by inflating costs to charges using the national average cost-to-charge ratio for routine days and $2,300 by inflating costs to charges using the pharmacy national average cost to charge ratio. The applicant recognized that accounting for anticipated savings is an imperfect process that requires assumptions be made on the best available evidence, and that given the absence of more detailed demographic data, CMS is correct in its uncertainty on whether the experiences of the 270 true-negative and false-negative patients included in the data from which savings were calculated can be adequately generalized to the Medicare population. However, the applicant pointed to a 2011 study published by the National Center for Health Statistics which found that rates of hospitalizations for septicemia or sepsis were significantly higher for those aged 65 and over than for those under age 65. Moreover, the applicant noted that, according to this study, the septicemia or sepsis hospitalization rate for those aged 85 and over was about 30 times the rate for those under age 65 and was more than four times higher than the rate for the 65–75 age group. Additionally, the study found that two-thirds of patients hospitalized for septicemia or sepsis in 2008 were aged 65 and over and had Medicare as their payer. The applicant concluded that while it cannot definitively say that the patient population in the study evaluating cost savings from use of Steripath is generalizable to the Medicare population, it is reasonable to assume that some portion of the patient population accounted for in the study would be representative of the Medicare population based on the high incidence of septicemia and sepsis among Medicare beneficiaries.

Finally, in response to our concern that the three percent of the applicant's sample population experience some level of savings is not the same as all cases in the sample experiencing three

percent savings, the applicant reran its cost analysis to randomly select three percent of cases from its full sample population and removed savings for those three percent of cases only. The applicant used the same methodology described previously to account for these savings. After randomly selecting three percent of cases from the full sample population and applying the anticipated savings from use of Steripath® Micro™ ISDD®, the applicant found that the final inflated case-weighted standardized charge per case exceeded the case-weighted threshold and that Steripath® Micro™ ISDD® meets the cost criterion.

Response: We thank the commenter for the additional information provided, including its supplementary cost analyses. After consideration of the comments received and the cost analyses provided by the appliant, we agree that the final inflated case-weighted standardized charge per case for Steripath® Micro™ ISDD® exceeds the case-weighted threshold and that Steripath® Micro™ ISDD® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the Steripath® Micro™ ISDD® represents a substantial clinical improvement over existing technology. The applicant stated that data from studies show that Steripath Micro™ ISDD® offers the ability to reduce blood collection contamination with skin flora and asserted that it improves clinical outcomes relative to services or technologies previously available as demonstrated by reducing clinically significant adverse events (that is, a decrease in inappropriate antibiotic use and a decrease in inappropriate hospitalizations).

The applicant submitted with its application 17 Steripath® ISDD® technology-specific studies, including 5 peer-reviewed studies published in scientific journals, that it stated support the contamination rate reduction with Steripath® Gen2 ISDD ® of 73.6 percent to 100 percent, with resulting sustained contamination rates of 0.97 percent to 0.0 percent, which the applicant stated is below the 3.0 percent gold standard benchmark rate for blood culture contamination.[386]

The applicant submitted a retrospective controlled study by Bell M, et al.[387] that showed that investigators seeking to lower the blood culture contamination rate at four different Lee Health (a healthcare system in Florida) emergency departments found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 83.0 percent when compared to conventional methods of sample acquisition, (that is without diversion). The Lee Health emergency departments compared contamination rates obtained using Steripath® Gen2 ISDD® device as the standard of care from May 2016 through November 2016 to conventional methods which were collected from October 2015 through November 2016. The applicant stated that these findings support their claim that Steripath® ISDD® reduces the risk of blood culture contamination.

The applicant submitted the Bauman, K, poster,[388] where investigators seeking to lower the blood culture contamination rate at the Inova Fairfax Medical Center found that Steripath® Gen2 implementation reduced their blood culture contamination rate by 81.5% when compared to conventional methods of sample acquisition. The trial use of Steripath® Gen2 lasted for one year, and results were compared to conventional methods for the year preceding the trial. According to the applicant, findings support the claim that Steripath® reduces the risk of blood culture contamination, while historical patient data from this hospital supported the claim that the lower contamination rate Steripath® enables will translate into a reduced patient length of stay of one day per avoided false positive event.

The applicant submitted the Blakeney J, et al.[389] poster, a prospective controlled study comparing the use of Steripath® ISDD® to standard collection methods and the effect on blood culture contamination rates. Over a 16-week period, participants' blood was collected using both the Steripath® and conventional methods, with each being recorded. Per the applicant, outcomes showed that Steripath® ISDD® implementation reduced Beebe Healthcare's blood culture contamination rate by 74.6 percent when compared to conventional methods of sample acquisition. The applicant stated that the findings support the claim that Steripath® ISDD® reduces the risk of blood culture contamination.

The applicant submitted the Church K, et al.[390] prospective controlled study, which showed that investigators at the Medical University of South Carolina emergency department found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 73.6 percent when compared to conventional methods of sample acquisition. In this 20-month study, nurses were given autonomy to decide if a patient would be best served by the Steripath® Gen2 device or conventional methods, with choices being recorded. The uptake rate of the Steripath® Gen2 device was 66%, with exclusions being uncooperative patients and difficult to stick patients.

The applicant submitted the Gauld L, et al.[391] study, an eight month long prospective controlled study which showed that investigators seeking to lower the blood culture contamination rate at the Medical University of South Carolina emergency department found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 86.3 percent when compared to conventional methods of sample acquisition.

The applicant submitted a poster, Lanteri C, et al.,[392] with preliminary data and a paper, Huss, J, et al.,[393] that includes all of the poster data with additional data gathered. This prospective controlled study at Brooke Army Medical Center showed that Steripath® Gen2 ISDD® implementation reduced blood culture contamination rate by 91.7 percent from September 2015 through January 2016, and 89.7 percent from September 2015 through March 2016 when compared to conventional methods of sample acquisition.

The applicant submitted the Rupp M, et al.[394] paper, which is a 12-month,

[386] Zimmerman, F. et al. ''Reducing blood culture contamination using an initial specimen diversion device.'' *American Journal of Infection Control* 47.7 (2019): 822–826.

[387] Bell M, et al. Effectiveness of a novel specimen collection system in reducing blood culture contamination rates. Journal of Emergency Nursing 44.6 (2018): 570–575.

[388] Bauman, K. ''Don't Stick Me Again! Reducing Blood Culture Contamination'' Poster presented at: Emergency Nursing Annual Conference

[389] Blakeney J, et al. ''Reduction of Blood Culture Contamination Using Initial Specimen Diversion Device''Poster presented at: American Society for Microbiology Annual Meeting (2018).

[390] Church K, et al. ''Novel Blood Culture Collection Device Reduces False-Positive Blood Cultures, Saves Costs, and Increases Accuracy of Bloodstream Infection Diagnosis'' Poster presented at: IHI National Forum (2017).

[391] Gauld L, et al. ''Reducing the laboratory cost of false-positive blood cultures in the adult emergency department.'' Poster presented at: IHI National Forum on Quality Improvement in Healthcare (2016).

[392] Lanteri C, et al. ''Reduction of Blood Culture Contaminations in the Emergency Department.'' Poster presented at: Department of Defense Healthcare Quality and Safety Awards (2016).

[393] Huss, Jody L, et al. ''Reducing Blood Culture Contamination with the Steripath® Blood Collection Kit.'' Uniformed Services University, 2016

[394] Rupp M, et al. ''Reduction in blood culture contamination through use of initial specimen diversion device.'' Clinical Infectious Diseases 65.2 (2017): 201–205.

single center, prospective, controlled, open label trial. Investigators at the University of Nebraska Medical Center emergency department seeking to gauge the efficacy of the Steripath® Gen2 ISDD® without confounding variables conducted a matched-set controlled study and found that Steripath® implementation reduced their blood culture contamination rate by 87.6 percent when compared to conventional methods of sample acquisition.

The applicant submitted the Stonecypher K, et al.[395] 8 week pilot study, which showed that investigators at the Michael E. DeBakey VA Medical Center emergency department found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 83.1 percent when compared to conventional methods of sample acquisition.

The applicant submitted the Tompkins L, et al.[396] abstract, which showed that investigators seeking to lower the blood culture contamination rate at Stanford Health Care found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 100 percent over a 4-month period when compared to conventional methods of sample acquisition. According to the applicant, full results are anticipated but not presently published.

The applicant submitted the Tongma C, et al.[397] prospective controlled study, which showed that investigators seeking to lower the blood culture contamination rate at Rush University Medical Center emergency department found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 87.0 percent when compared to conventional methods of sample acquisition. The 6-month study was split into an initial 3 months of usual care and a subsequent 3 months using the Steripath® Gen2 ISDD®.

The applicant provided the following studies to support secondary claims of substantial clinical improvement:

The applicant submitted the Buchta C, et al.[398] animal (pig) model study, in which investigators hypothesized that despite proper skin antiseptic use, contamination may occur because flora from deeper regions (such as pores) are not effectively eliminated. The applicant stated that results confirmed the hypothesis that cannula may cause tissue fragments to be punched in the process of blood sample acquisition, supporting the mechanism by which Steripath® Gen2 ISDD® primarily addresses blood culture contamination (that is, diversion).

The applicant submitted the Rhee C, et al.[399] retrospective cohort study, which featured adult patients admitted to 409 academic, community, and Federal hospitals from 2009–2014. Investigators sought to estimate national sepsis incidence and trends, concluding that sepsis was present in 6 percent of adult hospitalizations and 35 percent of hospitalizations resulting in death. According to the applicant, this helps put into context the role of Steripath® ISDD® in improving the efficacy of the primary tool used to guide therapy for bloodstream infections: Blood culture.

The applicant submitted the Zimmerman F, et al.[400] paper (a randomized clinical trial) and the Binkhamis K and Forward K[401] paper (a prospective controlled study), which demonstrated that manual diversion reduced blood culture contamination rate by 60.0 percent and 28.2 percent, respectively, when compared to conventional methods of sample acquisition.

The applicant also submitted the Patton R and Schmitt T[402] prospective controlled study, which showed that investigators seeking to trial manual diversion of 1 mL to lower the blood culture contamination rate at the Northwest Hospital and Medical Center Emergency Department found that manual diversion reduced their blood culture contamination rate by 43.8 percent when compared to conventional methods of sample acquisition. The applicant further stated that the findings additionally support the volume of diversion utilized by Steripath® Micro™ ISDD®.

The applicant also submitted the Syed S, et al.[403] preintervention and postintervention study, which showed that investigators at the AMITA Health Saint Francis Hospital Emergency Department found that manual diversion reduced their blood culture contamination rate by 30.9 percent when compared to conventional methods of sample acquisition.

According to the applicant, the findings from these four studies support the claim that manual diversion reduces the risk of blood culture contamination relative to conventional methods of sample acquisition. We note that these studies discussed manual diversion and not Steripath® Micro™ or other diversion devices.

The applicant submitted the Alahmadi Y, et al.[404] study, which is a retrospective case-control study that showed that false positive blood cultures were associated with an average 5.4 day increase in patient length of stay and average increases of more than $7,500 in total charges to a healthcare system. The applicant also submitted the Bates D, et al.,[405] which is a prospective controlled study that showed false positive blood cultures were associated with an average of a 4.5 day increase in patient length of stay and average increases of more than $4,000 in total charges to a healthcare system. According to the applicant, investigators also noted that contaminants were independently correlated with a 39 percent increase in antibiotic charges.

The applicant provided a study to support its claim that the Steripath® ISDD® reduces the average length of stay for patients requiring blood culture, thereby lowering their risk of hospital-acquired infections (HAI) and conditions (HAC). The applicant explained that the Skoglund E, et al.[406] decision tree health care economic model paper showed that investigators found that overall, each false positive blood culture was on average associated

[395] Stonecypher K, et al. ''ER Pilot Leads to Hospital-wide Implementation of Blood Culture Device'' Poster presented at: Emergency Nurses Association Annual Conference (2018)

[396] Tompkins L, et al. ''Eliminating Blood Culture Contamination with an Initial-Specimen Diversion Device'' Abstract presented at: IDWeek (2020).

[397] Tongma C, et al. ''Significant Reduction of Blood Culture Contamination in the Emergency Department (ED) Using the Steripath® Blood Diversion Device.'' Poster presented: Infectious Diseases Society of America IDWeek Conference, Fall (2017).

[398] Buchta C, et al. Skin plugs in phlebotomy puncture for blood donation. *Wiener klinische Wochenschrift* 117.4 (2005): 141–144.

[399] Rhee C, et al. Incidence and trends of sepsis in US hospitals using clinical vs claims data, 2009–2014. *JAMA* 318.13 (2017): 1241–1249.

[400] Zimmerman F, et al. Modification of blood test draw order to reduce blood culture contamination: A randomized clinical trial. *Clinical Infectious Diseases* 71.5 (2020): 1215–1220.

[401] Binkhamis K and Forward K. Effect of the initial specimen diversion technique on blood culture contamination rates. *Journal of Clinical Microbiology* 52.3 (2014): 980–981.

[402] Patton R and Schmitt T. Innovation for reducing blood culture contamination: Initial specimen diversion technique. *Journal of Clinical Microbiology* 48.12 (2010): 4501–4503.

[403] Syed S, et al. Diversion Principle Reduces Skin Flora Contamination Rates in a Community Hospital. *Archives of Pathology & Laboratory Medicine* 144.2 (2020): 215–220.

[404] Alahmadi Y, et al. Clinical and economic impact of contaminated blood cultures within the hospital setting. *Journal of Hospital Infection* 77.3 (2011): 233–236.

[405] Bates D, et al. Contaminant blood cultures and resource utilization: The true consequences of false-positive results. *JAMA* 265.3 (1991): 365–369.

[406] Skoglund E, et al. Estimated clinical and economic impact through use of a novel blood collection device to reduce blood culture contamination in the emergency department: A cost-benefit analysis. *Journal of Clinical Microbiology* 57.1 (2019).

with 2 day increases in patient length of stay and an average increase of more than $4,500 in total charges to a healthcare system. According to the applicant, Steripath® ISDD® implementation may reduce costs associated with contamination and reduce the average patient length of stay.

The applicant provided four studies to support its claim that Steripath® ISDD® reduces the inappropriate administration of vancomycin and other antibiotics to drive antibiotic stewardship. The applicant submitted the Chang D, et al.[407] poster, a retrospective, nonrandomized study that recorded the San Antonio Military Medical Center Emergency Department's days of therapy (DOT) of vancomycin for 18 months as a baseline. Then, the hospital implemented a new blood culture test, and recorded the DOT of vancomycin for 7 months. Subsequently, the hospital implemented the Steripath® Gen2 device and recorded the DOT of vancomycin for an additional 14 months to complete the 39-month trial. Investigators found that Steripath® Gen2 ISDD® implementation reduced vancomycin days of therapy by 14.4 days per 1,000 patient days when compared to conventional methods of sample acquisition. According to the applicant, findings from the study, as reported by the study authors, support the claim that Steripath® ISDD® reduces the unnecessary administration of antibiotics by reducing the rate of false positive blood cultures.

The applicant also submitted the Souvenir D, et al.[408] cohort study of 3,276 cultures of blood from 1,433 patients in which investigators found that physicians treated almost half of all patients receiving a false positive blood culture result with antibiotics, with vancomycin misuse occurring in 34 percent of patients. The applicant also submitted the Heijden Y, et al.[409] study in which investigators found that physicians treated 27% of patients receiving a false positive blood culture result with antibiotics unnecessarily, with the median antibiotic regimen being 7 days in length. The applicant also submitted the Bates study,[410] as discussed previously, which showed contaminants were independently correlated with a 39 percent increase in antibiotic charges. According to the applicant, as Steripath® ISDD® is designed to reduce the incidence of blood culture contamination, Steripath® ISDD® implementation may reduce unnecessary antibiotic administration while supporting antimicrobial stewardship.

In the proposed rule (86 FR 25320 through 25321), we stated the following concerns regarding the substantial clinical improvement criterion. We noted that much of the evidence submitted by the applicant to support that Steripath® Micro™ represents a substantial clinical improvement over existing technologies spoke to the overall clinical value of reducing blood contamination, or the benefit of manual diversion over no diversion, but did not directly link the Steripath® Micro™ to improved clinical endpoints. We noted that the applicant stated that all of the studies provided that address the specific technology used to reduce blood contamination through diversion of the initial sample during blood collection utilized the Steripath® Gen2 ISDD®, not the Steripath® Micro™ ISDD® and we therefore question whether we have sufficient information to assess the clinical impact of Steripath® Micro™. Furthermore, we noted that the applicant did not present any clinical data to compare Steripath® Micro™ ISDD® to the Steripath® Gen2 ISDD®. We also noted that comparative studies between Steripath® Micro™ and either manual diversion or competitor devices were not provided, and we question whether the standard of care used in the studies (that is, no diversion) is an appropriate comparator against which to test this technology. Additionally, we noted that the applicant did not provide any clinical data demonstrating that the Steripath® Micro™ directly reduced length of stay, *C. difficile* infections, or other secondary results of antibiotic overuse. We noted our interest in any clinical data that directly links the Steripath® Micro™ to these outcomes.

Finally, we noted that the claim of gentle negative pressure in support of the applicant's assertion that the technology would provide a treatment option for a new patient population was not addressed by any of the studies submitted. In addition, no data was supplied that quantified appropriate levels of negative pressure for either the typical or DIVA populations. Furthermore, no data was provided which compared the asserted appropriate level of negative pressure to levels of negative pressure created by the Steripath® Micro™ and Steripath® Gen2 devices. We noted our interest in any evidence of clinical improvement using the Steripath® Micro™ ISDD® in the specific population identified by the applicant, the difficult intravenous access population.

We invited public comments on whether the Steripath® Micro™ ISDD® meets the substantial clinical improvement criterion.

Comment: The applicant submitted a letter that asserted the Steripath® Micro™ ISDD® meets the substantial clinical improvement criteriona. The applicant stated that the Steripath® Micro™ ISDD® meets the CMS regulatory definition of ''substantial clinical improvement'' because it offers the DIVA, hypovolemic, hypotensive, and small-in-stature populations access to a technology for which these groups currently have no other available option. Per the applicant, Steripath® Micro™ ISDD® confers the same benefits of the Steripath® Gen2 ISDD® onto new patient populations. The applicant further stated that Steripath® Micro™ ISDD® initial results (over 500 blood culture draws with zero contaminations at multiple facilities) indicate an efficacy profile substantially equivalent to Steripath Gen2 ISDD®.

In response to our concern regarding the lack of clinical data for the Steripath® Micro™ ISDD®, the applicant reiterated that the reduced diversion volume is supported by the literature,[411] initial data indicates a substantially equivalent efficacy profile, the DIVA population is eligible for the device, and the FDA cleared the Steripath® Micro™ ISDD® with specific indications for use to reduce blood culture contamination.

In response to our concern regarding the lack of studies that compare the Steripath® Micro™ ISDD® to any relevant standard of care or technology, the applicant stated that studies provided by the applicant regarding manual diversion can be compared to studies featuring the Steripath® Gen2 ISDD®, despite the studies taking place in different times, settings, and patient populations. The applicant further stated that the initial results since the commercial launch of the Steripath®

[407] Chang D, et al. ''Impact of blood culture diversion device on molecular pathogen identification on vancomycin use.'' Poster presented at: Society for Healthcare Epidemiology of America (2017).

[408] Souvenir D, et al. Blood cultures positive for coagulase-negative staphylococci: Antisepsis, pseudobacteremia, and therapy of patients. *Journal of Clinical Microbiology* 36.7 (1998): 1923–1926.

[409] Heijden, Yuri F., et al. ''Clinical impact of blood cultures contaminated with coagulase-negative staphylococci at an academic medical center. Infection Control and Hospital Epidemiology 32.6 (2011): 623.

[410] Bates D, et al. Contaminant blood cultures and resource utilization: The true consequences of false-positive results. *JAMA* 265.3 (1991): 365–369.

[411] Patton, Richard G., and Timothy Schmitt. ''Innovation for reducing blood culture contamination: Initial specimen diversion technique.'' Journal of Clinical Microbiology 48.12 (2010): 4501–4503.

Micro™ ISDD® are equivalent to the Steripath® Gen2 ISDD®. The applicant also notes that there are no FDA-cleared competitive devices that are indicated to reduce blood culture contamination. The applicant also stated that no diversion is the standard of care and therefore an appropriate comparator.

In response to our concern that there is no evidence linking the Steripath® Micro™ ISDD® directly to reduced length of stay, *C. difficile* infections, or other secondary results of antibiotic overuse, the applicant stated that the equivalent efficacy of the Steripath® Micro™ ISDD® to the Steripath® Gen2 ISDD® indicated that the Steripath® Micro™ ISDD® will have equivalent effects on outcomes demonstrated by use of Steripath® Gen2 including reduced blood culture contamination,[412] reduced length-of-stay [413] and reduced antibiotic use.[414]

In response to our concerns regarding the lack of quantifiable data related to the pressure of the devices, the applicant noted that the Steripath® Micro™ ISDD® novel bladder architecture utilizes 78% lower average peak negative pressure compared to Steripath Gen2 ISDD® (average range of −0.5 psi compared to −2.3 psi) to help reduce the risk of vascular compromise and/or interrupted blood flow during blood culture collection.

We also received additional comments in support of the technology. A commenter noted that in their hospital's experience with using the Steripath® Micro™ ISDD® in pediatric patients, no contaminations have occurred. Another commenter stated that the Steripath® Micro™ ISDD® will allow their health system to reduce blood contamination equitably across populations as it serves the DIVA population who was previously ineligible for Steripath® ISDD® technology.

Response: We appreciate the commenters' perspectives on the substantial clinical improvement criterionaand have taken them into consideration. However, after review of all the data received to date, we continue to have concerns regarding the substantial clinical improvement criterion as noted in the FY 2022 IPPS/LTCH PPS proposed rule. Specifically, we remain concerned that the applicant did not provide any studies that featured the Steripath® Micro™ ISDD®, which is the subject of this application, and we therefore cannot adequately determine if the product fully meets the substantial clinical improvement criterion. While the applicant stated that initial results of blood draws with Steripath® Micro™ indicate a substantially equivalent efficacy profile to that of the Gen2, we did not receive any data to support this claim, and furthermore, substantial equivalence does not demonstrate superiority. We agree that existing FDA-cleared devices are not indicated to reduce blood culture contamination and are therefore not an appropriate comparator. Though the applicant compared blood culture contamination reduction rates of manual diversion as compared to Steripath® Gen2 and asserted that the Micro™ has been proven to perform as well as Gen2, without data using the Steripath® Micro™ to demonstrate improved outcomes we are unable to come to this conclusion. Thus, we also continue to have concerns that the applicant also did not provide studies that compared the Steripath® Micro™ ISDD® to other Steripath® devices (specifically Steripath® Gen2) or other forms of diversion or best practices used to reduce blood culture contamination to demonstrate an improvement in clinical outcomes such as length of stay, treatment decisions, *C. difficile* infections, or other secondary results of antibiotic overuse, as the applicant only reiterated evidence linking the Steripath® Gen2 to these outcomes. Though the applicant asserts that the Micro®'s comparable efficacy to the Gen2 gives them no reason to believe these outcomes will be affected with the DIVA population, we disagree that this is a new patient population as discussed further below, and believe that this does not speak to the technology's superiority over existing technologies.

We also continue to have concerns with the applicant's assertion that Steripath® Micro™ treats patients ineligible for current treatments. As discussed previously, the applicant's website states that the Gen2 is also targeted to treat DIVA patients, and patients with difficult access are still able to receive blood cultures. The applicant states that the standard of care is no diversion, and therefore it follows that these patients will not require it to receive blood cultures using other forms of best practices. Since we did not receive any data demonstrating the use of Steripath® Micro® in DIVA patients, we are unable to determine that it offers a treatment option for patients ineligible for current therapies.

After consideration of the information previously submitted in the Steripath® Micro™ ISDD® application and previously summarized in this final rule, and the public comments we received, we are unable to determine that the Steripath® Micro™ ISDD® meets the substantial clinical improvement criterion. Therefore, we are not approving new technology add-on payments for the Steripath® Micro™ ISDD® for FY 2022.

m. StrataGraft™ Skin Tissue

Stratatech Corporation, a Mallinckrodt company, submitted an application for new technology add-on payments for the StrataGraft™ skin tissue (''StrataGraft'') for topical application for FY 2022. The applicant describes StrataGraft™ skin tissue as a viable, bioengineered, regenerative skin construct (BRSC) consisting of an epidermal layer of viable, fully stratified, allogeneic human NIKS® [415] keratinocytes growing on a dermal layer composed of viable human dermal fibroblasts embedded in a collagen-rich matrix. The applicant noted that StrataGraft™ is intended for the treatment of adult patients with severe thermal burns that contain intact dermal elements and require surgical intervention (hereinafter referred to as severe thermal burns [STB]). The applicant stated that StrataGraft™ skin tissue is produced in a rectangular format of approximately 100 cm^2, approximately 8 cm by 12.5 cm.

The applicant explained that the StrataGraft™ skin tissue promotes durable wound closure and regenerative healing for adult patients with STB. The applicant stated that in addition to providing immediate wound coverage and epidermal barrier function, the viable and metabolically active keratinocytes and fibroblasts in StrataGraft™ skin tissue provide sustained expression and secretion of growth factors, cytokines, and wound healing factors, which are anticipated to promote regenerative healing. The applicant stated that the StrataGraft™ skin tissue does not engraft; rather, it promotes regenerative healing and is replaced by the patient's own cells, eliminating the need for autografting to attain definitive closure of treated wounds.

The applicant explained that a thermal burn is the most common type

[412] Doern G, et al. A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem. Clinical Microbiology Reviews. 2020; 33:e00009–19.

[413] Bauman, K. ''Don't Stick Me Again! Reducing Blood Culture Contamination'' Poster presented at: Emergency Nursing Annual Conference.

[414] Chang D, et al. ''Impact of blood culture diversion device on molecular pathogen identification on vancomycin use.'' Poster presented at: Society for Healthcare Epidemiology of America (2017).

[415] Registered trademark of Stratatech Corporation, Madison, WI.

of burn injury and accounts for approximately 86 percent of burn cases.[416] The applicant noted that burns are classified according to the depth of tissue injury as superficial (first-degree burns), partial-thickness (superficial and deep partial-thickness; second-degree burns), full-thickness (FT, third-degree burns), and fourth-degree burns (burns that have injured deeper structures such as muscle, fascia, and bone).[417] [418] The applicant also noted the percentage of total body surface area (TBSA) determines burn severity and directly correlates with mortality.[419]

The applicant stated that in the U.S., approximately 500,000 burn injuries receive emergency medical treatment each year, leading to 40,000 burn injury hospitalizations with 30,000 at hospital burn centers.[420] [421] The applicant noted that children and the elderly represent especially vulnerable populations at increased risk for death due to the skin loss and its complications.[422] The applicant explained that in 2013, the rate of burn-related hospital stays was highest for infants aged younger than 1 year (29.6 per 100,000 population) and older adults (20.7 per 100,000 population for adults aged 65–84 and 26.3 per 100,000 population for adults aged 85 and older).[423] The applicant also stated that unintentional fire or burn injuries was the 8th leading cause of death in those 65 years or older.[424]

The applicant explained that today, 96.7 percent of burn patients treated in burn centers will survive. The applicant noted that many of those survivors will sustain serious scarring and life-long physical disabilities.[425] The applicant stated that burn injuries pose a significant burden to patients; they can have a considerably negative effect on the patient's health-related quality of life (HRQoL), which was estimated to be reduced by 30 percent at the time of injury and by 9 percent in the long term.[426] The applicant explained that although most functional domains affected by burn injuries recover over time, HRQoL scores pertaining to physical and emotional role participation, anxiety, depression, pain, work, and heat sensitivity remained low at 12 months after the injury.[427]

The applicant explained that the standard of care for STB injuries is early excision and skin grafting.[428] [429] [430] The applicant noted that common surgical interventions for burn injury include: Escharotomy, debridement, excision, and skin grafting.[431] The applicant explained that these burns have been treated with autografts, allografts, and xenografts in the past. The applicant stated that autologous grafts (autografts) are used most frequently because of the problems of infection and rejection when using allografts or xenografts.[432]

The applicant explained that autografting involves surgical harvesting of healthy tissue from the patient (donor site) and transplantation of this skin to an injured site on the same patient.[433] The applicant noted that autografts can be harvested as split thickness or full thickness. According to the applicant, split-thickness skin grafts (STSGs), also called partial-thickness grafts, transfer a portion of the donor site skin, including the epidermis and some of the underlying dermis. The applicant also explained that this allows the donor site to heal from the epidermal elements left behind. The applicant also stated that full-thickness skin grafts (FTSGs) harvest the entire layer of skin as the graft; no dermal or epidermal elements remain at the donor site, which must be closed by local advancement of the adjoining skin or by a secondary local flap. The applicant stated that the process of revascularization takes longer for an FTSG than for an STSG because of the increased thickness of the tissue.[434]

The applicant explained that early excision and skin grafting reduce the chance of wound infections and systemic sepsis, and have become the standard of care.[435] [436] [437] The applicant noted that without autografting, an STB that contains some dermal elements usually requires greater than 3 weeks to heal, thereby increasing the risk for infection and other complications that may lead to the development of significant scarring and contracture.[438] [439] [440] The applicant stated that while STBs require surgical debridement and grafting, superficial first-degree burns do not;[441] however, in the acute phase of the burn injury,

[416] Schaefer TJ, Tannan SC. Thermal Burns. [Updated 2020 Jun 7]. In: StatPearls [internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. *https://www.ncbi.nlm.nih.gov/books/NBK430773//.*

[417] Kagan RJ, Peck MD, Ahrenholz DH, et al. Surgical management of the burn wound and use of skin substitutes: An expert panel white paper. J Burn Care Res. 2013;34(2):e60–e79.

[418] Rice PL, Orgill DP. Assessment and classification of burn injury. UpToDate. *https://www.uptodate.com/contents/assessment-and-classification-of-burn-injury.* Literature review current through September 2020. Accessed September 25, 2020.

[419] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[420] Burn Injury Fact Sheet. American Burn Association. *https://ameriburn.org/wp-content/uploads/2017/12/nbawfactsheet_121417-1.pdf.* Published February 2018. Accessed July 1, 2020.

[421] HCUPnet, Healthcare Cost and Utilization Project. Agency for Healthcare Research and Quality, Rockville, MD. *https://hcupnet.ahrq.gov/.* Accessed June 5, 2019.

[422] Burn Injury Fact Sheet. American Burn Association. *https://ameriburn.org/wp-content/uploads/2017/12/nbawfactsheet_121417-1.pdf.* Published February 2018. Accessed July 1, 2020.

[423] McDermott KW, Weiss AJ, Elixhauser A. Burn-Related Hospital Inpatient Stays and Emergency Department Visits, 2013: Statistical Brief #217. 2016 Dec. In: Healthcare Cost and Utilization Project (HCUP) Statistical Briefs [internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2006 Feb. *https://www.ncbi.nlm.nih.gov/books/NBK409513/.* Accessed September 30, 2020.

[424] Burn Injury Fact Sheet. American Burn Association. *https://ameriburn.org/wp-content/uploads/2017/12/nbawfactsheet_121417-1.pdf.* Published February 2018. Accessed July 1, 2020.

[425] Burn Injury Fact Sheet. American Burn Association. *https://ameriburn.org/wp-content/uploads/2017/12/nbawfactsheet_121417-1.pdf.* Published February 2018. Accessed July 1, 2020.

[426] Miller T, Bhattacharya S, Zamula W, et al. Quality-of-life loss of people admitted to burn centers, United States. Qual Life Res. 2013;22(9):2293–2305.

[427] Spronk I, Legemate C, Oen I, van Loey N, Polinder S, van Baar M. Health related quality of life in adults after burn injuries: A systematic review. PLoS One. 2018;13(5):e0197507. Published 2018 May 24.

[428] Bittner EA, Shank E, Woodson L, Martyn JA. Acute and perioperative care of the burn-injured patient. Anesthesiology. 2015;122(2):448–464.

[429] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[430] Ibid.

[431] Kagan RJ, Peck MD, Ahrenholz DH, et al. Surgical management of the burn wound and use of skin substitutes: An expert panel white paper. J Burn Care Res. 2013;34(2):e60–e79.

[432] Shevchenko RV, James SL, James SE. A review of tissue-engineered skin bioconstructs available for skin reconstruction. J R Soc Interface. 2010;7(43):229–258.

[433] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[434] Leon-Villapalos J. Skin autografting. UpToDate. *https://www.uptodate.com/contents/skin-autografting.* Literature review current through September 2020. Accessed October 1, 2020.

[435] Bittner EA, Shank E, Woodson L, Martyn JA. Acute and perioperative care of the burn-injured patient. Anesthesiology. 2015;122(2):448–464.

[436] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[437] Id.

[438] Deitch EA, Wheelahan TM, Rose MP, Clothier J, Cotter J. Hypertrophic burn scars: Analysis of variables. J Trauma. 1983;23(10):895–898.

[439] Kagan RJ, Peck MD, Ahrenholz DH, et al. Surgical management of the burn wound and use of skin substitutes: An expert panel white paper. J Burn Care Res. 2013; 34(2):e60–79.

[440] Shupp JW, Nasabzadeh TJ, Rosenthal DS, Jordan MH, Fidler P, Jeng JC. A review of the local pathophysiologic bases of burn wound progression. J. Burn Care Res. 2010; 31(6):849–873.

[441] Bittner EA, Shank E, Woodson L, Martyn JA. Acute and perioperative care of the burn-injured patient. Anesthesiology. 2015;122(2):448–464

the clinical presentation of the severely injured burn patient usually involves a range of burn depths from a superficial burn to a FT burn.[442]

The applicant explained that although autografting is effective in closing wounds and has been a standard treatment for decades, it has limitations. The applicant stated that donor sites are often associated with several complications, including excessive pain, pruritus, infection, dyschromia, hypertrophic scarring, delayed healing, and the potential for conversion to a FT wound.[443] The applicant also noted that donor-site pain is typically more painful than that in the treatment (burned) site and may become chronic.[444] [445] In patients with burns of 50–60 percent TBSA, autograft is limited by donor-site availability.[446] The applicant explained that donor sites may be re-harvested if they heal in time without infection; however, this practice can lead to prolonged hospitalization and decreased quality of the skin from re-harvested sites. The applicant stated that after patients undergo skin grafting, in the long term, both the grafted wound site and the donor site require continuous physical and rehabilitative therapy to maintain the range of movement, minimize scar and contracture development, and maximize functional ability.[447]

The applicant noted that autografting is especially undesirable in vulnerable patient populations, such as the elderly. The applicant stated that the healing of donor sites may be delayed or even lacking in elderly patients or patients whose wound-healing capabilities are compromised.[448] The applicant explained that because patients in these populations have thinner dermis and epidermis than non-elderly adults,[449] [450] there is a higher likelihood that the donor sites will go deep into the dermis during harvest or transform into FT wounds with their anatomical characteristics. The applicant stated that these patients are disproportionately affected and are at increased risk for death due to the skin loss and its complications.[451] The applicant also noted that the American College of Surgeons (ACS) developed guidelines to educate surgeons and other medical professionals about the significance of older adult burns and evidence-based prevention activities.[452]

The applicant stated that burn injuries result in substantial economic burden for healthcare systems and society. The applicant noted the average total hospital charges for a surviving patient with burns was estimated to be $98,062 and a patient who did not survive burns was estimated at $309,546.[453] For patients undergoing inpatient autografting, the applicant asserted that significant healthcare costs were observed during the first year, including per patient mean all-cause healthcare costs which ranged from $155,272 to $184,805.[454] The applicant explained that the primary cost driver in the first year was the cost incurred from the initial inpatient episode with autografting, accounting for 85 percent of the total costs.[455]

The applicant stated in their application that there is currently no skin replacement product approved or available that leads to durable wound closure while eliminating the need for harvesting an autograft.[456] [457]

The applicant explained that skin substitutes are a heterogeneous group of biologic, synthetic, or biosynthetic materials that can provide temporary or permanent coverage of open skin wounds. The applicant stated that the aim of skin substitutes is to replicate the properties of the normal skin,[458] and to provide the protective barrier function until definitive closure of the skin.[459] The applicant noted that synthetic skin substitutes need to be removed or undergo biodegradation or resorption so the skin can heal and regenerate.[460] The applicant also stated that biological skin substitutes have an architecture that resembles native skin and may allow the construction of a more natural new dermis.[461]

The applicant explained that skin substitutes are an important adjunct in the management of acute or chronic wounds and can be used to cover defects following burns or other injuries, or for reconstruction, such as for release of extensive severe post-burn contractures.[462] [463] The applicant also stated that Kumar's 3-category system, as shown in the table that follows, is currently the most frequently used classification system in the field. However, the applicant notes that there is no universally accepted classification system that allows for simple categorization of all the products that are commercially available.[464] The applicant stated that several biologic and biosynthetic materials are currently used as skin substitutes to temporarily cover wounds. The applicant provided the following table which, according to the applicant, classifies skin substitutes according to Kumar (2008) and summarizes the applicant's assertions regarding existing skin substitute products.

[442] Ibid.

[443] 4 Osborne SN, Schmidt MA, Harper JR. An Automated and Minimally Invasive Tool for Generating Autologous Viable Epidermal Micrografts. Adv Skin Wound Care. 2016;29(2):57–64.

[444] Birchall MA, Varma S, Milward TM. The Moriarty sign: An appraisal. Br J Plast Surg. 1991;44(2):149–150.

[445] Sinha S, Schreiner AJ, Biernaskie J, et al. Treating pain on skin graft donor sites. J. Trauma Acute Care Surg. 2017;83(5)954–964.

[446] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[447] Procter F. Rehabilitation of the burn patient. Indian J Plast Surg. 2010;43(Suppl):S101–S113.

[448] Bradow BP, Hallock GG, Wilcock SP. Immediate Regrafting of the Split Thickness Skin Graft Donor Site Assists Healing. Plast Reconstr Surg Glob Open. 2017;5(5):e1339. Published 2017 May 23.

[449] King A, Balaji S, Keswani SG. Biology and function of fetal and pediatric skin. Facial Plast Surg Clin North Am. 2013;21(1):1–6.

[450] Wainwright DJ, Bury SB. Acellular dermal matrix in the management of the burn patient. Aesthet Surg J. 2011;31(7 Suppl):13S–23S.

[451] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

[452] Statement on Older Adult Burn Prevention. American College of Surgeons (ACS). *https://www.facs.org/aboutacs/statements/81-older-adult-burn.* Published January 1, 2018. Accessed September 26, 2020.

[453] American Burn Association. National Burn Repository 2019 update. 2019.

[454] Yu TC, Zhang X, Smiell J, Zhou H, Tan R, Boing E, Tan H. Healthcare resource utilization, treatment patterns, and cost of care among patients with thermal burns and inpatient autografting in two large privately insured populations in the United States. Burns. 2020;46(4):825–835.

[455] Ibid.

[456] Kagan RJ, Peck MD, Ahrenholz DH, et al. Surgical management of the burn wound and use of skin substitutes: An expert panel white paper. J Burn Care Res. 2013;34(2):e60–e79.

[457] Carter JE, Holmes JH. The Surgical Management of Burn Wounds. 2016.

[458] Shahrokhi S. Skin substitutes. UpToDate. *https://www.uptodate.com/contents/skin-substitutes.* Literature review current through August 2020.

[459] MacNeil S. Progress and opportunities for tissue-engineered skin. Nature 2007;445(7130)874–880.

[460] Halim A, Khoo T, Shah JY. Biologic and synthetic skin substitutes: An overview. Indian J. Plast. Surg. 2010;43(3)23.

[461] Ibid. Halim A, Khoo T, Shah JY. Biologic and synthetic skin substitutes: An overview. Indian J. Plast. Surg. 2010;43(3)23.

[462] Shahrokhi S. Skin substitutes. UpToDate. *https://www.uptodate.com/contents/skin-substitutes.* Literature review current through August 2020.

[463] Leon-Villapalos J. Skin autografting. UpToDate. *https://www.uptodate.com/contents/skin-autografting.* Literature review current through September 2020. Accessed October 1, 2020.

[464] Shahrokhi S. Skin substitutes. UpToDate. *https://www.uptodate.com/contents/skin-substitutes.* Literature review current through August 2020. Accessed September 25, 2020.

Skin substitute classification according to Kumar (2008)[465]				
Class	**Description**	**Sub-Category**	**Subdivision**	**Product Example**
I	Temporary, impervious dressing material with mecahnical traits of the epidermis; lack keratinocytes	Single Layered Materials	Naturally occurring membrane or cover as biological dressing substitute	Biomembrane® Biocompatible vegetal membranes derived from the Hevea brasiliensis rubber tree
			Single-layer synthetic skin dressing material substitute	Tegaderm™, Opsite™, Dermafilm™, Nexfill®
		Bi-layered tissue-engineered materials		TransCyte®
II	Single-layer skin substitutes (epidermal or dermal)	Epidermal substitutes - similar to human epidermis; prone to breakdown; poor healing outcomes		Epice®, EpiDex®, Laserskin®, MySkin™, BioSeed®, CellSpray™
		Dermal substitutes - composition that includes proteins found in the dermal matrix		Permacol®, Matriderm®, Alloderm®
III	Composite skin substitutes that replace both the dermal and epidermal layer	Skin graft (autografts, allografts, and xenografts)		Allograft from cadaver, xenograft from porcine origin
		Tissue-engineered skin		Apligraf® (cellular), Integra® (acellular), Biobrane®

The applicant stated that StrataGraft™ skin tissue is a novel BRSC which possesses many of the physical and biological properties of an ideal skin substitute, including both epidermis and dermis with a barrier function comparable to that of intact human skin.[466] The applicant asserted that upon FDA approval, StrataGraft™ skin tissue will be the only skin substitute for treatment of STB classified by the FDA as a biologic (as opposed to other available treatments that are medical devices) that promotes durable wound closure and regenerative healing, thereby reducing or eliminating the need of autologous skin harvesting. According to the applicant, on June 5, 2020, Mallinckrodt finalized the rolling submission of a Biologics License Application (BLA) to the FDA seeking approval to market StrataGraft™ skin tissue for the treatment of adult patients with STB. On June 15, 2021, the FDA approved Stratagraft™ for the treatment of adult patients with thermal burns containing intact dermal elements (remaining deep skin layers) for which surgical intervention is clinically indicated (also referred to as deep partial thickness burns). The applicant submitted a request for a unique ICD–10–PCS code for the use of Stratagraft™ beginning FY 2022 and was granted approval to use the following ICD–10–PCS code effective October 1, 2021: XHRPXF7 (Replacement of skin with bioengineered allogeneic construct, external approach, new technology group 7).

The applicant explained that StrataGraft™ skin tissue is a viable BRSC that may be applied universally to patients, that is, it is not a patient-specific product. The applicant stated that the active cellular components of StrataGraft™ skin tissue are the viable and metabolically active allogeneic human NIKS® keratinocytes and normal human dermal fibroblasts (NHDF).

The applicant noted that StrataGraft™ skin tissue comprises an epidermal layer and a dermal layer. The

[465] Kumar P. Classification of skin substitutes. Burns. 2008;34(1)148–149.

[466] Schurr MJ, Foster KN, Centanni JM, et al. Phase I/II clinical evaluation of StrataGraft: A consistent, pathogen-free human skin substitute. J Trauma. 2009;66(3):866–874.

applicant explained that the epidermal layer of StrataGraft™ skin tissue is composed of differentiated, multilayered, viable epidermal keratinocytes that are adherent through normal hemidesmosomes to a dermal equivalent.[467] The applicant stated that human epidermal keratinocytes used are NIKS® keratinocytes, a continuous and consistent source of well-characterized, non-tumorigenic, long-lived keratinocyte precursors that are derived from a single neonatal human foreskin donor. The applicant asserted that NIKS® keratinocytes have normal steady state of messenger ribonucleic acid (mRNA) and protein expression levels for autocrine regulators and growth factors such as transforming growth factor (TGF)-α, TGF-β1, epidermal growth factor, and c-myc, providing further evidence of the normal function of these cells.[468] The applicant also explained that NIKS® keratinocytes produce normal adhesion proteins (example, integrins and cadherins) that permit tight adherence to each other and the dermal equivalent.[469] The applicant stated that cell-cell and cell-substratum adhesions confer excellent handling characteristics to StrataGraft™ skin tissue, enabling it to be meshed and secured in place as is routinely done with STSGs. The applicant noted that the dermal layer of StrataGraft™ skin tissue contains NHDF derived from a single healthy tissue donor.

The applicant explained that viable cells within StrataGraft™ skin tissue express and secrete a wide variety of peptides, growth factors, and cytokines that are known to promote healing, thereby reducing or eliminating the need for autograft in the management of thermal burns.[470] The applicant also stated that no currently available technology (competitor) for the treatment of STB is characterized by the autologous (endogenous) tissue regeneration of the burned skin.

The applicant stated that the StrataGraft™ skin tissue is manufactured through organotypic culture under aseptic conditions in compliance with current Good Manufacturing Practices. The applicant explained that in organotypic culture, NIKS® keratinocytes undergo tissue-appropriate differentiation and stratification to produce a skin tissue that exhibits many of the structural and biological properties of intact human skin. The applicant noted that the epidermal layer of StrataGraft™ skin tissue exhibits typical production and organization of cell-type specific proteins (example, keratin, filaggrin, involucrin, and transglutaminase), development of a normal cornified envelope, and production of lipid-filled granules that are necessary for the generation and maintenance of robust epidermal barrier function similar to that found in vivo.[471]

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, the mechanism of action of StrataGraft™ skin tissue in severe thermal burns is not the same or similar to an existing technology. The applicant states that StrataGraft™ skin tissue will be the first and only FDA-approved biologic for the treatment of STB that reduces or eliminates the need of autograft and for which the mechanism of action is a sustained expression and secretion of growth factors, cytokines, and wound healing factors, which are anticipated to promote regenerative healing and durable wound closure.[472] [473] The applicant explains that this unique mechanism of action is the reason StrataGraft™ skin tissue reduces or eliminates the need for harvest of donor site tissue.

With respect to the second criterion, whether a product would be assigned to the same MS–DRGs as existing technologies, the applicant indicated that the StrataGraft™ skin tissue would be assigned to the same MS–DRGs as cases representing patients who receive standard of care (autograft) or existing technologies used to treat STB. The applicant stated that the MS–DRGs in question do not differentiate between patients with burns of differential severity degree, in different body sites, due to thermal injury or corrosion, or with different percent TBSA involved.[474]

With respect to the third criterion, whether a product would be used to treat the same or similar type of disease and patient population, the applicant asserted that StrataGraft™ will treat the same or similar type of disease but not the same or similar patient population when compared to existing technologies. The applicant claimed that StrataGraft™ skin tissue will treat a burn patient population for whom the current standard of care and/or other available technologies may not be clinically feasible solutions to achieve durable wound closure. The applicant explains that in patients with burns of 50–60 percent of the TBSA, donor-site availability is limited.[475] The applicant also stated that autografting is especially undesirable in vulnerable patient populations, such as the elderly; healing of donor sites may be delayed or even lacking in elderly patients or patients whose wound-healing capabilities are compromised.[476] The applicant explained that these patients are disproportionately affected and are at increased risk for death due to the skin loss and its complications.[477] The applicant also states that the label for StrataGraft™ skin tissue will not be reserved for a patient population diagnosed with STB for whom standard-of-care treatment is not feasible or clinically desirable. The applicant asserts that this does not imply that StrataGraft™ skin tissue will not offer a treatment option to a new patient population.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 PR 25321 through 25329), we noted that with respect to the first criterion, there may be other biologic dressings that use some combination of keratinocytes, collagen,

[467] Schurr MJ, Foster KN, Centanni JM, et al. Phase I/II clinical evaluation of StrataGraft skin tissue: A consistent, pathogen-free human skin substitute. J Trauma. 2009;66(3):866-874.

[468] Allen-Hoffmann BL, Schlosser SJ, Ivarie CA, Sattler CA, Meisner LF, O'Connor SL. Normal growth and differentiation in a spontaneously immortalized near-diploid human keratinocyte cell line, NIKS. J Invest Dermatol. 2000;114(3):444–455

[469] Ibid.

[470] Harvestine J, Pradhan-Bhatt S, Steiglitz BM, Maher RJ, Comer AR, Gratz KR, Allen-Hoffmann BL. StrataGraft® Skin Tissue, a Bioengineered Regenerative Skin Construct for Severe Acute Wounds. Poster presented at: 2020 Biomedical Engineering Society (BMES) Virtual Annual Meeting, October 14–17, 2020.

[471] Ibid.

[472] Proposed prescribing information. for Stratagraft™ skin tissue;. Submitted to FDA, April 2020.

[473] Harvestine J, Pradhan-Bhatt S, Steiglitz BM, Maher RJ, Comer AR, Gratz KR, Allen-Hoffmann BL. StrataGraft® Skin Tissue, a Bioengineered Regenerative Skin Construct for Severe Acute Wounds. Poster presented at: 2020 Biomedical Engineering Society (BMES) Virtual Annual Meeting, October 14–17, 2020.

[474] MDC 22 Burns. Non-Extensive Burns. In: ICD–10–CM/PCS MS–DRG v37.2 Definitions Manual. Centers for Medicare & Medicaid Services. *https://www.cms.gov/icd10m/version372-fullcode-cms/fullcode_cms/P0353.html.* Accessed October 1, 2020.

[475] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[476] Bradow BP, Hallock GG, Wilcock SP. Immediate Regrafting of the Split Thickness Skin Graft Donor Site Assists Healing. Plast Reconstr Surg Glob Open. 2017;5(5):e1339. Published 2017 May 23.

[477] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

glycosaminoglycans (GAGs), cytokines, chemokines, and/or other growth factors in either a single, double, or triple layer configuration. While StrataGraft™ may have a unique combination of these features, we stated that we were interested in further information on whether there are any dressings with a regenerative mechanism of action that may be approved for burns.

With respect to the third criterion, we stated that we believed that StrataGraft™ may treat the same or similar patient population as the standard of care or existing technologies to treat STB. While we agreed that in patients with burns of 50–60 percent of the TBSA, donor-site availability is more limited, we observed that neither of the two pivotal studies included patients with burns of 50 percent or greater of the TBSA.[478] We were unclear whether this suggests Stratagraft™ is intended for treatment of patients with burns of less than 50 percent TBSA. We also questioned whether vulnerable patients, such as the elderly, are a new population as they are currently treated using standard of care or other technologies.

We invited public comments on whether Stratagraft™ is substantially similar to other technologies and whether Stratagraft™ meets the newness criterion.

Comment: The applicant submitted a public comment responding to our concerns. With respect to our concerns that StrataGraft™ may have a similar mechanism of action to other biologic dressings, the applicant stated that StrataGraft™ is an allogeneic cellularized scaffold product and the first-ever FDA-approved biologic (drug) product indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (DPT burns). The applicant stated that StrataGraft™ incorporates a unique, biodegradable barrier layer which does not require physical removal at some point after its application. The applicant stated that StrataGraft™ supports the body's ability to heal itself by providing metabolically active cells that are gradually replaced by the patient's own cells, and releasing the cytokines and growth factors associated with the stimulation of healing. The applicant stated that the manner in which StrataGraft™ supports healing is distinct from that of autograft, which is reflected in the speed at which healing takes place—complete healing of DPT burns treated with StrataGraft™ may lag autografting by a few weeks.

The applicant stated that several medical devices may be available to Medicare beneficiaries who are receiving treatment for burns; however, a device, by definition, achieves ''its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes''. The applicant stated that such devices are so classified as they are all products in some way supplemented with cells (the active ingredient). The applicant stated that in contrast, StrataGraft is a biologic drug product, its own active ingredient, and a functional unit at the time of delivery whose functions are to (i) secrete growth factors and cytokines by the viable cells of the mature tissue to facilitate wound repair and regenerative healing; and (ii) protect the wound bed by serving as a natural protective epidermal barrier. The applicant noted that the actions of the various constituents of StrataGraft are synergic and cannot be separated. The applicant stated that input collagen is a structural component that provides a biologically relevant environment which enables cellular maturation and paracrine signaling between the NIKS keratinocytes and human dermal fibroblasts (NHDF) during manufacture, resulting in epidermal differentiation and dermal compartment organization with endogenous synthesis of human extracellular matrix (ECM) proteins. The applicant stated that since StrataGraft is both (i) its own active ingredient and (ii) unique, its mechanism of action cannot be the same or similar to that of any existing technology. The applicant noted that StrataGraft does not share an active ingredient with any other product—the FDA established a whole new active ingredient descriptor for StrataGraft as part of its assignment of the Unique Ingredient Identifier (UNII) code.

The applicant noted that StrataGraft supports the body's ability to heal itself by (i) providing metabolically active cells that are gradually replaced by the patient's own cells, and (ii) releasing the cytokines and growth factors associated with the stimulation of healing. The applicant stated that cells incorporated into StrataGraft are sourced from the NIKS keratinocyte cell line—a proprietary, single-source, karyotypically stable, nontumorigenic, and pathogen-free human keratinocyte progenitor that provides a stable, source of donor tissue. The applicant asserted that NIKS is not present in any other technology available to Medicare beneficiaries for the treatment of burns or any other type of wounds. The applicant stated that this newness is reflected in the FDA's designation of StrataGraft as a regenerative medicine advanced therapy (RMAT)—the only RMAT-designated product for the treatment of burns; a drug is eligible for RMAT designation if it is a ''regenerative medicine therapy''.

The applicant stated that StrataGraft™ incorporates a unique, biodegradable allogenic cellularized scaffold comprised of a purified murine Type I collagen matrix embedded with fibroblasts that is not present in any medical device, and is eventually replaced by the patient's own tissue. The applicant noted that a second procedure to remove StrataGraft™ is not required.

In response to our concern regarding the applicability of StrataGraft™ to a new patient population of >50% TBSA burns, the applicant stated that although StrataGraft™ was not studied in patients with more than 50% total body surface area (TBSA) burns in STRATA2011 or STRATA2016, this was due to the intrapatient comparator trial design and is not a limitation of the product. The applicant also noted that separate from the STRATA2011 and STRATA2016 clinical trials, StrataGraft™ was used to treat four adult patients as part of the FDA Single Patient Expanded Access Program (EAP). The applicant stated that two of these patients had burns >50% TBSA and one had a major burn (40% TBSA). The applicant stated that two out of three patients had successful wound closure, and one patient died three weeks post-surgery for reasons unrelated to StrataGraft™ treatment. The applicant noted that one additional request was received for a 74-year-old male with 65% TBSA flame burn with inhalation injury, but this patient became unstable and succumbed to his injuries prior to excision and grafting of his burn wounds.

In response to our concern regarding StrataGraft™ treating a new subpopulation, the elderly, the applicant reiterated the undesirability of treating elderly patients with the current standard of care—autograft—primarily due to co-morbidities or decreased skin thickness. The applicant also highlighted that diabetic patients may have impaired wound healing, making the harvest of an autograft particularly undesirable. The applicant stated that elderly patients have thinner dermis and epidermis than do non-elderly adults, and their skin is prone to tears and bruising, which complicates donor

[478] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

autograft harvesting. The applicant stated that StrataGraft™ is the only skin substitute product FDA-approved for DPT thermal burns of any TBSA that does not require donor skin harvest and/or subsequent autografts. The applicant asserted that other technologies, such as Integra, Epicel, and RECELL all require some degree of skin harvest. The applicant stated that the need for new, autograft-sparing treatments in this patient population is reflected in the FDA's decision to allow StrataGraft to be used as part of the EAP, which the FDA characterizes as a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

The applicant noted that because StrataGraft™ does not have to be removed, there is no potential for skin injury similar to that potentially experienced during removal of other products. The applicant stated that the directions for use for Epicel note that its backing layer must be removed after the procedure seven to ten days after grafting with extreme care to prevent damage to the graft. The applicant noted that directions for use for RECELL caution providers to use extreme care when removing dressings to ensure that it is atraumatic. Additionally, the applicant notes that Integra incorporates a silicone layer that must be removed about twenty-one days after application, and prior to autografting, in a separate procedure.

Several commenters asserted that StrataGraft™ will be the only DPT burn treatment that is an FDA-approved biologic (drug) product capable of achieving durable wound closure by 3 months similar to autograft, while eliminating autograft harvest in 96% of patients; is in receipt of Regenerative Medicine Advanced Therapy (RMAT) designation; and is characterized by a mechanism of action which leverages the regenerative capacity of the patient's skin. Several commenters also asserted that prior to the approval of StrataGraft™, the only FDA-approved skin substitutes were medical devices that required either initial donor harvest (for example, Epicel® and RECELL®) or a subsequent autograft (for example, Integra®) for promoting wound closure.

Response: We appreciate the commenters' input on the newness of StrataGraft™ and the additional information from the applicant in regard to the newness criterion. We agree that StrataGraft™ utilizes a unique mechanism of action among FDA approved treatments for DPT burns because it is a regenerative technology that allows growth of the patient's own tissue until it is completely replaced, while functioning as a protective barrier. We believe this is different than autografting and other burn treatments that require skin harvest and become incorporated, with the skin healing around it. We thank the applicant for providing examples of patients with burns of 50% or more TBSA treated with StrataGraft™ though these patients were excluded from the clinical trials. However, we note that this patient population is not excluded from the standard of care or other technologies, such as Epicel, which is indicated for use in patients with burns of 30% or greater TBSA. Further, we note that we do not consider the elderly a new patient population in regard to the use of StrataGraft™ as they are currently not excluded from the standard of care or other technologies. Therefore, we believe that StrataGraft™ treats the same or similar patient population as existing technologies.

After consideration of the public comments we received and information submitted by the applicant as part of its FY 2022 new technology add-on payment application for StrataGraft™, we agree with the applicant and commenters that StrataGraft™ has a unique mechanism of action. Therefore, we believe that StrataGraft™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the newness period to begin on June 15, 2021 when StrataGraft™ was approved by the FDA.

With regard to the cost criterion, the applicant stated in their application that StrataGraft™ skin tissue is seeking FDA approval for the proposed indication of treatment of adult patients with STBs that contain intact dermal elements and require surgical intervention. In order to identify the range of MS–DRGs that eligible patients may map to, the applicant conducted a claims search for cases that include ICD–10–CM codes for thermal burns of second, third degree, or those classified according to TSBA to identify cases eligible for use of StrataGraft™ skin tissue utilization. The applicant identified cases reporting ICD–10–CM codes for diagnoses of second-degree thermal burns, any location (T20.2XXX to T25.2XXX); third-degree thermal burns, any location (T20.3XXX to T25.3XXX); and thermal burns classified according to extent of body surface involved (T31.XX).

The applicant used the FY 2019 MedPAR Hospital LDS with the FY 2022 thresholds, and the FY 2019 IPPS/LTCH Final Rule Impact File and Standardizing File. The applicant's claim search in the aggregate identified 58,624 cases mapping to 21 MS–DRGs as listed in the following table. Of the total 21 MS–DRGs, only six had case volume greater than or equal to one percent across all cohorts and cumulatively represent 97.54 percent of cases. In cases where MS–DRGs had fewer than 11 discharges, the applicant imputed a minimum value of 11 cases for each MS–DRG.

Potential MS-DRGs Expected To Be Assigned To StrataGraft™ Skin Tissue-Eligible Inpatient Cases Listed In Descending Order According To Case Volume	
MS-DRG	**Description**
928	Full Thickness Burn w Skin Graft or Inhalation Injury w CC/MCC
929	Full Thickness Burn w Skin Graft or Inhalation Injury w/o CC/MCC
927	Extensive Burns or Full Thickness Burns w Mv >96 Hours w Skin Graft
935	Non-Extensive Burns
003	Ecmo or Tracheostomy w Mv >96 Hours or Pdx Except Face, Mouth And Neck w Major O.R. Procedure
940	O.R. Procedure w Diagnoses of Other Contact w Health Services w CC
904	Skin Grafts For Injuries w CC/MCC
941	O.R. Procedures w Diagnoses of Other Contact w Health Services w/o CC/MCC
939	O.R. Procedures w Diagnoses of Other Contact w Health Services w MCC
577	Skin Graft Except For Skin Ulcer or Cellulitis w CC
574	Skin Graft For Skin Ulcer or Cellulitis w CC
853	Infectious & Parasitic Diseases w O.R. Procedure w MCC
901	Wound Debridements for Injuries w MCC
246	Percutaneous Cardiovascular Procedures w Drug-Eluting Stent w MCC Or 4+ Arteries or Stents
166	Other Respiratory System O.R. Procedures w MCC
906	Hand Procedures for Injuries
264	Other Circulatory System O.R. Procedures
573	Skin Graft for Skin Ulcer or Cellulitis w MCC
464	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders w CC
004	Tracheostomy w Mv >96 Hours or Pdx Except Face, Mouth and Neck w/o Major O.R. Procedure
854	Infectious and Parasitic Diseases w O.R. Procedure w CC

To demonstrate that the technology meets the cost criterion, the applicant first identified four separate patient cohorts: Cohort (1) Patients with thermal burns of second or third degree in any body area, or thermal burns classified according to TBSA, who received autograft for reasons only related to thermal burns (n=14,774, MS–DRGs=21); Cohort (2) Patients with thermal burns of second or third degree in any body area, or thermal burns classified according to TBSA, who received autograft for reasons only related to thermal burns, and who underwent excisional debridement in the inpatient setting (n=13,640, MS–DRGs=20); Cohort (3) Patients with thermal burns of second or third degree in any body area, or thermal burns classified according to TBSA, who received autograft for thermal burns, with or without other conditions (n=15,744, MS–DRGs=21); and Cohort (4) Patients with thermal burns of second or third degree in any body area, or thermal burns classified according to TBSA, who received autograft for thermal burns, with or without other conditions, and who underwent excisional debridement in the inpatient setting (n=14,466, MS–DRGs=20). The applicant then identified eight analyses for the cost criterion: (1) Calculations for Cohort one (all MS–DRGs); (2) Calculations for cohort two (all MS–DRGs); (3) Calculations for Cohort three (all MS–DRGs); (4) Calculations for cohort four (all MS–DRGs); (5) Calculations for Cohort one (top 4 MS–DRGs by case volume); (6) Calculations for Cohort two (top 4 MS–DRGs by case volume); (7) Calculations for Cohort three (top 4 MS–DRGs by case volume);

and (8) Calculations for Cohort 4 (top 4 MS–DRGs by case volume).

The applicant determined an average unstandardized case weighted charge per case of $173,650 for analysis one, $168,282 for analysis two, $178,530 for analysis three, $172,277 for analysis four, $158,851 for analysis five, $155,700 for analysis six, $162,377 for analysis seven, and $158,452 for analysis eight.

The applicant stated that charges for and related to the prior technologies were not removed from the cost analysis.

After calculating the average standardized charge per case for all scenarios, the applicant calculated the standardized charge per case for each MS–DRG. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges of 13.2 percent (1.13218). The applicant stated that the price for Stratagraft™ skin tissue has not yet been established and therefore it did not add charges for the technology. Lastly, the applicant calculated the final average inflated standardized charge per case and the inflated case weighted standardized charge per case for each scenario.

The applicant stated that, for analysis one, the final inflated average case-weighted standardized charge per case of $304,347 exceeded the average case-weighted threshold amount of $173,650 by $130,697. For analysis two, the final inflated average case-weighted standardized charge per case of $279,373 exceeded the average case-weighted threshold amount of $168,282 by $111,091. For analysis three, the final inflated average case-weighted standardized charge per case of $332,006 exceeded the average case-weighted threshold amount of $178,530 by $153,477. For analysis four, the final inflated average case-weighted standardized charge per case of $299,228 exceeded the average case-weighted threshold amount of $172,277 by $126,951. For analysis five, the final inflated average case-weighted standardized charge per case of $241,186 exceeded the average case-weighted threshold amount of $158,851 by $82,336. For analysis six, the final inflated average case-weighted standardized charge per case of $229,661 exceeded the average case-weighted threshold amount of $155,700 by $73,961. For analysis seven, the final inflated average case-weighted standardized charge per case of $257,800 exceeded the average case-weighted threshold amount of $162,377 by $95,423. For analysis eight, the final inflated average case-weighted standardized charge per case of $244,042 exceeded the average case-weighted threshold amount of $158,452 by $85,590.

The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, Stratagraft™ meets the cost criterion.

We invited public comment on whether StrataGraft™ meets the cost criterion.

Comment: A commenter, the applicant, maintained that StrataGraft™ meets the cost criterion because, across several cost analysis scenarios, the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount.

Response: We appreciate the applicant's response. Based on the applicant's cost analysis as previously summarized and consideration of the comment received, we agree that the average case-weighted standardized charge per case exceeds the average case-weighted threshold amount. Therefore, StrataGraft™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that StrataGraft™ skin tissue is a substantial clinical improvement over existing technology for the treatment of adult patients with severe thermal burns with intact dermal elements because it achieves a significant rate of durable wound closure for patients with severe burns while minimizing or eliminating the complications associated with autograft harvest.

According to the applicant, the totality of the circumstances otherwise demonstrates that StrataGraft™ skin tissue, relative to technologies previously available, substantially improves the treatment of STB patients including Medicare beneficiaries. The applicant stated that because the benefits associated with its use are not accompanied by an increased incidence of adverse events as compared to autograft, StrataGraft™ skin tissue is a substantial clinical improvement. The applicant explained that by significantly reducing or eliminating the harvest of donor sites, patients who receive StrataGraft™ skin tissue are spared short- and long-term sequelae and complications and, to a lesser extent, infection or conversion to a full-thickness wound of the donor sites.[479] The applicant stated that by significantly reducing or eliminating the need for autograft,[480] StrataGraft™ skin tissue is especially relevant for the elderly population where autograft is undesirable; these patients are disproportionately affected and are at increased risk for death due to the skin loss and its complications.[481] The applicant explained that aging and environmental factors can influence the severity of burns in vulnerable skin.[482] [483] The applicant stated that geriatric skin also exhibits slower wound healing and is at increased risk of excessive scarring.[484] [485] [486] [487] [488] According to the applicant, age-related changes in wound healing capacity can include delayed infiltration of immune cells, decreased secretion of growth factors, and altered collagen remodeling.[489]

The applicant further explained that use of StrataGraft™ skin tissue can preserve limited donor sites for the treatment of other wounds, such as areas of FT injury and wounds in cosmetically sensitive areas. The applicant noted that it may also reduce the need for repeated harvest of autograft donor sites, potentially reducing the number of surgical procedures and total length of time to wound closure. The applicant explained that burn injury is associated with a high prevalence of posttraumatic stress disorder, ranging between 11 percent and 50 percent across studies,[490] and may also lead to anxiety and depression due to scarring and body image concerns.[491] Lastly, the applicant stated

[479] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

[480] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[481] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

[482] Gosain A, DiPietro LA. Aging and wound healing. World J Surg. 2004;28(3):321–326.

[483] Landau M. Exogenous factors in skin aging. Curr Probl Dermatol. 2007;35:1–13.

[484] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

[485] Gosain A, DiPietro LA. Aging and wound healing. World J Surg. 2004;28(3):321–326.

[486] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

[487] Ibid.

[488] Gosain A, DiPietro LA. Aging and wound healing. World J Surg. 2004;28(3):321–326.

[489] Ibid.

[490] Summer G J, Puntillo KA, Miaskowski C, et al. Burn Injury Pain: The Continuing Challenge. J. Pain 2007;8(7)533–548.

[491] Calotă DR, Nițescu C, Marinescu S, et al. Correlations between morphological appearance

Continued

that use of StrataGraft™ skin tissue reduces pain while offering a comparable scar quality to autograft.[492]

The applicant provided two controlled and randomized studies, STRATA2011 and STRATA2016, to support its claims of substantial clinical improvement. The applicant stated that with the exception of subject age (STRATA2011, 18 to 64 years of age; STRATA2016, ≥18 years of age), the inclusion and exclusion criteria for the two studies were similar. According to the applicant, the STRATA2016 study (NCT03005106—Phase 3 trial—71 patients)[493] [494] was a 12-month, open-label, multicenter, controlled, randomized study that evaluated the efficacy and safety of StrataGraft™ skin tissue in promoting autologous skin tissue regeneration of severe thermal burns. The applicant explained that the STRATA2011 study (NCT01437852—Phase 1b trial—30 patients)[495] [496] was a 12-month, open-label, multicenter, controlled, randomized, dose-escalation study that evaluated the safety, tolerability, and efficacy of StrataGraft™ skin tissue in promoting the healing of the STB component of complex skin defects due to thermal injury as an alternative to autografting. The applicant noted that, in both studies, eligible subjects had 3 percent to 49 percent TBSA burns with two comparable treatment sites that were prospectively identified, and the sites were randomized to receive either a single topical application of StrataGraft™ skin tissue or autograft, such that each subject received both treatments. The applicant noted that in this intrapatient comparator design, the area that was autografted served as a subject's own paired control.

To support the claim that the use of StrataGraft™ skin tissue significantly reduces the percent area of the treatment sites autografted, the applicant explained that the STRATA2016 study showed the average percent area of the StrataGraft™ skin tissue treatment site autografted by Month 3 was lower than the average percent area of the autograft control treatment site autografted by Month 3 (mean difference: 97.77 percent; $P < 0.0001$).[497] We note that the applicant did not provide detailed information regarding the measurement methodology.

To support the claim that StrataGraft™ skin tissue is effective in achieving durable wound closure similar to that of autografting, the applicant states that the STRATA2016 study showed that the majority of subjects (59 of 71 subjects, or 83.1 percent, with a 95 percent CI of 74.4 to 91.8) achieved durable wound closure of the StrataGraft™ skin tissue-treated site at Month 3 without the need for autograft harvest and placement.[498] The applicant also explained that the STRATA2011 study showed that no StrataGraft™ treatment sites required autografting by Day 28. The applicant noted that at Month 3 in the STRATA2016 study, 93.1 percent of StrataGraft™ treatment sites were assessed as closed. The applicant stated that all StrataGraft™ skin tissue-treated areas evaluated at 6 months and 12 months remained closed. The applicant noted that, when comparing these results to that of autografting, the proportion of wounds that achieved closure was not statistically different.[499]

To support the claim of reduction in donor site pain using StrataGraft, the applicant stated that the STRATA2016 study showed that the difference between the donor sites preserved for StrataGraft™ skin tissue treatment site failure and autograft donor sites in the average pain intensity through Day 14 based on the Wong-Baker FACES® Pain Rating Scale (FPRS)[500] was 2.40 ± 1.313 ($P < 0.0001$), indicating significantly less mean donor-site pain intensity in the reserved StrataGraft™ skin tissue donor sites compared with autograft donor sites.[501] The applicant also stated that the STRATA2011 study showed that patients experienced pain at harvested donor sites used for autograft, but minimal pain at unharvested donor sites that had been set aside for potential use with StrataGraft™ skin tissue.[502]

According to the applicant, the elimination of autografting leads to superior scar quality outcome of the presumptive StrataGraft™ skin tissue donor site (that is lack of scarring in the donor sites reserved for StrataGraft™ treatment site failure), which is a substantial clinical improvement. The applicant explained that the STRATA2016 study showed that the evaluation of scarring using the Patient and Observer Scar Assessment Scale (POSAS)[503] [504] observer total scores demonstrated a significant difference in scar quality between the StrataGraft™ skin tissue and autograft donor sites at Month 3, 10.0 ± 7.92 ($P < 0.0001$), favoring StrataGraft™ skin tissue.[505] The applicant stated that the STRATA2016 study showed scores for every POSAS category were lower for StrataGraft™ skin tissue donor sites when compared with autograft donor sites, indicating they were more like normal skin (that is, the patient's tissue in the donor sites reserved for StrataGraft™ failure were more like normal skin than tissue present in autograft donor sites that were harvested).[506] The applicant explained that the STRATA2011 study showed

and psychosocial difficulties in patients with extensive burns who received allotransplant. Rom J Morphol Embryol. 2012;53(3 Suppl):703–711.

[492] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[493] StrataGraft skin tissue® Skin Tissue in the Promotion of Autologous Skin Regeneration of Complex Skin Defects Due to Thermal Burns That Contain Intact Dermal Elements. *ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03005106.* Accessed June 15, 2020.

[494] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[495] StrataGraft skin tissue® Skin Tissue as an Alternative to Autografting Deep Partial-Thickness Burns. *ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT01437852.* Accessed June 15, 2020.

[496] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[497] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[498] Ibid.

[499] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[500] Wong-Baker FACES Foundation. *https://wongbakerfaces.org/.* Accessed July 1, 2020.

[501] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[502] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[503] Van de Kar AL, Corion LUM, Smeulders MJC, et al. Reliable and Feasible Evaluation of Linear Scars by the Patient and Observer Scar Assessment Scale. Plast. Reconstr. Surg. 2005;116(2)514–522.

[504] The Patient and Observer Scar Assessment Scale (POSAS). *https://www.posas.nl/.* Accessed July 1, 2020.

[505] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[506] Ibid.

that observer POSAS total scores from the StrataGraft™ tissue treatment site and autograft were not significantly different throughout the study.[507] The applicant stated that the STRATA2011 showed that mean overall POSAS opinion scores of observers or patients decreased (that is, became more favorable) from Month 3 through Month 12 after application for both the StrataGraft™ tissue and autograft.[508]According to the applicant, although direct comparisons between StrataGraft™ skin tissue and other skin substitutes cannot be drawn, StrataGraft™ skin tissue, relative to device technologies previously available, improves the clinical outcomes of STB patients. The applicant stated that most skin substitutes do not claim to promote wound closure without the need for subsequent autograft because they have not been studied in this context,[509] while clinical studies for StrataGraft™ skin tissue assessed wound closure as a pre-specified endpoint.[510] [511] The applicant further stated that reparative healing mechanisms, used by most available skin substitutes, are more likely to result in scarring when compared with regenerative healing mechanisms used by StrataGraft™.[512]

In the proposed rule (86 FR 25329), after reviewing the information provided by the applicant with regard to the substantial clinical improvement criterion, we noted a lack of study data provided comparing StrataGraft™ to other biologic dressings and stated that we were interested in further information related to whether there are any dressings that may be approved for burns that demonstrate durable wound closure. The applicant provided published results of one randomized trial (STRATA2011), but we questioned whether the sample size of 30 is adequately generalizable to the larger Medicare population. In addition, we noted that the STRATA2016 study has not been published and the results of this study were not submitted in full, and we therefore may not have the complete outcomes and study results for these additional patients. We further noted that in the studies provided, patients with 50 percent or greater TBSA burns were excluded. The applicant indicated that the product could be especially meaningful for patients with burns of 50–60 percent TBSA, but we questioned whether we can fully evaluate this claim because these patients were not assessed.

We invited public comments on whether StrataGraft™ meets the substantial clinical improvement criterion.

Comment: In its comment, the applicant stated that, subsequent to publication of the FY 2022 proposed rule, the full results of the STRATA2016 trial were published. The applicant provided a copy of the study in full. Seventy-one adult patients aged 19 to 79 who sustained 3% to 37% TBSA thermal burns on the torso, arms, or legs were enrolled in the phase 3 clinical trial. In each patient, two DPT areas of comparable depth were randomized to either StrataGraft™ or autograft. The study results indicated that the safety profiles, cosmesis, and durable wound closure of autograft and StrataGraft™ are similar, but StrataGraft™ is associated with a significant reduction in donor site harvesting. StrataGraft™ eliminated the need for autograft donor site harvesting in 96% of cases. Since StrataGraft™ eliminates the need for harvesting a donor site in most patients, typical donor site sequelae such as pain and scarring were also reduced.

In response to our concern regarding autograft as the only study comparator, the applicant noted that StrataGraft™ is the only product to have demonstrated not just durable wound closure, but autograft-sparing durable wound closure in clinical trials, and that is FDA-approved for the treatment of DPT burns in adults. The applicant noted that when treating DPT burns, durable wound closure is just one treatment goal. Other treatment goals include mitigating sequelae such as scarring, scar-complications, and infections; autografts are a major source of these sequelae.

In response to our question about the generalizability of the sample size, the applicant provided the STRATA2016 [513] study with an additional 71 patients. The applicant also noted that the percentage of patients >65 years old is in line with clinical trial composition of other products that have previously received new technology add-on payments.

Several commenters stated that StrataGraft™ reduces donor site pain and scarring, and achieves clinically similar cosmesis to autograft at the treatment site in a single procedure. Several commenters also noted that StrataGraft™ has the potential to reduce repeated hospitalizations by limiting or even eliminating sequelae associated with donor site morbidities. Several commenters stated that autografting is especially undesirable in elderly patient populations because of compromised wound healing, comorbidities, and risk of complications. The commenters asserted that these patients also have a thinner dermis and epidermis compared to younger adults.

Response: We thank the commenters for their input and have taken these comments into consideration. We also thank the applicant for its comment as well as the provision of the newly published study and additional information. After review of the information provided, we agree with the applicant and commenters that StrataGraft™ demonstrates substantial clinical improvement by facilitating durable wound closure without the need for skin harvest and/or autograft. Because StrataGraft™ does not any require any skin harvest, it also reduces the necessity for additional healing sites, as well as the additional scarring and pain that come along with it. For this reason, we believe it offers a valuable treatment option for patients at risk for poor wound healing and complications.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that StrataGraft™ meets the criteria for approval of the new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2022.

[507] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[508] Ibid.

[509] Stone Ii R, Natesan S, Kowalczewski CJ, et al. Advancements in Regenerative Strategies Through the Continuum of Burn Care. Front Pharmacol. 2018;9:672. Published 2018 Jul 9.

[510] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[511] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[512] Hu MS, Maan ZN, Wu JC, et al. Tissue engineering and regenerative repair in wound healing. Ann Biomed Eng. 2014;42(7):1494–1507.

[513] Gibson ALF, Holmes JH 4th, Shupp JW, Smith D, Joe V, Carson J, Litt J, Kahn S, Short T, Cancio L, Rizzo J, Carter JE, Foster K, Lokuta MA, Comer AR, Smiell JM, Allen-Hoffmann BL. A phase 3, open-label, controlled, randomized, multicenter trial evaluating the efficacy and safety of StrataGraft® construct in patients with deep partial-thickness thermal burns. Burns. 2021 Apr 23:S0305–4179(21)00110–8. doi: 10.1016/j.burns.2021.04.021. Epub ahead of print. PMID: 34099322.

Cases involving the use of StrataGraft™ that are eligible for new technology add-on payments will be identified by ICD–10– PCS procedure code XHRPXF7 (Replacement of skin with bioengineered allogeneic construct, external approach, new technology group 7). The applicant stated that the cost per sheet of StrataGraft™ is $4,000. According to the applicant, the per-patient utilization for StrataGraft™ is based on a 10 percent burn of a 1700cm² body surface area skin burn: 17000 cm² (average adult body surface area) × 10% = 1700 cm² burned body area. This translates to an average of 17 sheets needed per patient case involving the use of StrataGraft™ (1700 cm² burned body area/100 cm² StrataGraft skin tissue sheet = 17 sheets). The applicant noted that the number of sheets needed may vary from one patient to the next, based on the size of the burn injury and therefore size of the StrataGraft-treated area.

The applicant estimated that the average cost of StrataGraft™ to the hospital is $6,800 (17 sheets × $4000 per sheet). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the costs of the new medical service or technology, or 65 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, the maximum new technology add-on payment for a case involving the use of StrataGraft™ is $44,200 for FY 2022.

n. TECARTUS® (brexucabtagene autoleucel)

Kite Pharma submitted an application for new technology add-on payment for FY 2022 for TECARTUS® (brexucabtagene autoleucel). TECARTUS® is a CD19 directed genetically modified autologous T-cell immunotherapy for the treatment of adult patients with relapsed and refractory (r/r) mantle cell lymphoma (MCL). We noted that Kite Pharma previously submitted an application for new technology add-on payments for TECARTUS® for FY 2021, as summarized in the FY 2021 IPPS/LTCH PPS proposed rule, under the name KTE–X19 (85 FR 32634).

TECARTUS® is a form of chimeric antigen receptor (CAR) T-cell immunotherapy that modifies the patient's own T-cells to target and eliminate tumor cells. More specifically, according to the applicant, TECARTUS® is a single infusion product consisting of autologous T-cells that have been engineered to express an anti-CD19 chimeric antigen receptor. According to the applicant, this therapy targets the CD19 antigen on the cell surface of normal and malignant B-cells. The applicant stated that TECARTUS® is different from other previously approved technologies because it has a distinct cellular product that requires a unique manufacturing process.

According to the applicant, Mantle Cell Lymphoma (MCL) is a rare and aggressive subtype of non-Hodgkin lymphoma (NHL) with distinct characteristics [514] [515] that accounts for 3–10% of all cases of NHL in the United States and differs from diffuse large B-cell lymphoma (another subtype of NHL).[516] [517] [518] The applicant stated that MCL has an annual incidence of 0.5 to 1 cases per 100,000 population with a male-to-female ratio of 3:1 with a median age at diagnosis for patients with MCL of 68 years.[519] MCL results from a malignant transformation of the B lymphocyle in the outer edge of a lymph node follicle (the mantle zone). Prognosis varies for relapsed/refractory MCL, but the median survival for MCL is 3–5 years depending on the risk group (the Mantle Cell Lymphoma International Prognostic Index categorizes patients into low, intermediate and high risk groups), according to the applicant.[520] According to the applicant, the preferred first line therapy is bendamustine- rituximab which has decreased toxicity and improved progression-free survival as compared to rituximab with cyclophosphamide, doxorubicin, vincristine, and prednisone.[521] According to the applicant, rituximab is also the only approved therapy for maintenance for patients in remission. The applicant stated the median progression free survival ranges from 29–51 months with most of MCL patients eventually relapsing. The applicant contended that approximately 40% of patients end up with durable long-term remission after a chemoimmunotherapy first line therapy.[522] [523] [524]

The applicant indicated that there is no standard of care that exists for second-line and higher chemotherapy when a patient has relapsed or refractory MCL.[525] According to the applicant, second line therapies typically depend on the front-line therapy utilized, comorbidities, the tumor's sensitivity to chemotherapy, and overall risk-benefit. According to the applicant, currently available options for second line therapy include: Cytotoxic chemotherapy, proteasome inhibitors (PI), immunomodulatory drugs (IMiD), tyrosine kinase inhibitors, and stem cell transplant (both autologous and allogenic stem cell transplant [ASCT, allo-SCT]). According to the applicant, Bruton's tyrosine kinase (BTK) inhibitors, ibrutinib, zanubrutinib, and acalabrutinib, are common third-line therapy used for patients with r/r MCL and have shown to offer improvements over other chemotherapy-based regimens for r/r MCL patients. The applicant performed a literature review and meta-analysis of patients with r/r MCL whose disease had progressed during or following treatment with a BTK inhibitor and found that despite high initial response rates, most patients eventually developed progressive disease. Therefore, according to the applicant, new therapeutic strategies are needed to improve the prognosis of patients with r/r MCL whose disease has not been effectively controlled with chemo-immunotherapy, stem cell transplant, and BTK inhibitors.

[514] Fakhri B, Kahl B. Current and emerging treatment options for mantle cell lymphoma. Ther Adv Hematol. 2017;8(8):223–34.

[515] National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology; B-cell Lymphomas, Version 1.2019 [November 30, 2018]. 2017 Available from: *https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.*

[516] The Non-Hodgkin's Lymphoma Classification Project. A clinical evaluation of the International Lymphoma Study Group classification of non-Hodgkin's lymphoma. Blood. 1997;89(11):3909–3918.

[517] Zhou Y, et al. Incidence trends of mantle cell lymphoma in the United States between 1992 and 2004. Cancer. 2008;113(4):791–798.

[518] Teras LR, et al. 2016 US lymphoid malignancy statistics by World Health Organization subtypes CA Cancer J Clin. 2016;6:443–459.

[519] Fu S, et al. Trends and variations in mantle cell lymphoma incidence from 1995 to 2013: A comparative study between Texas and National SEER areas. Oncotarget. 2017;8(68):112516–29.

[520] Cheah CY, et al. Mantle cell lymphoma. *J Clin Oncol.* 2016;34:1256–1269.

[521] Rummel MJ, et al. Bendamustine plus rituximab versus CHOP plus rituximab as first-line treatment for patients with indolent and mantle-cell lymphomas: An open-label, multicentre, randomized, phase 3 non-inferiority trial. Lancet. 2013;381: 1203–1210.

[522] Flinn IW, et al. First-line treatment of patients with indolent non-Hodgkin lymphoma or mantle-cell lymphoma with bendamustine plus rituximab versus R–CHOP or R–CVP: Results of the BRIGHT 5-year follow-up study. *J Clin Oncol.* 2019 Apr 20;37(12):984–991. doi: 10.1200/JCO.18.00605. Epub 2019 Feb 27.

[523] LaCasce AS, et al. Comparative outcome of initial therapy for younger patients with mantle cell lymphoma: an analysis from the NCCN NHL Database. *Blood.* 2012;19(9):2093–2099.

[524] Lenz G, et al. Immunochemotherapy with rituximab and cyclophosphamide, doxorubicin, vincristine, and prednisone significantly improves response and time to treatment failure, but not long-term outcome in patients with previously untreated mantle cell lymphoma: Results of a prospective randomized trial of the German Low Grade Lymphoma Study Group (GLSG). J Clin Oncol. 2005:23(9): 1984–1992.

[525] Campo E, Rule S. Mantle cell lymphoma: Evolving management strategies. *Blood.* 2015;125(1):48–55.

With respect to the newness criterion, the applicant indicated that the FDA approved the TECARTUS® Biologics License Application (BLA) on July 24, 2020 for the indication of the treatment of adult patients with relapsed/refractory mantle cell lymphoma (MCL). According to the applicant, TECARTUS® was granted Breakthrough Therapy designation for the treatment of patients with r/r MCL on June 15, 2018 and received Orphan Drug designation in 2016 for the treatment of MCL, acute lymphoblastic leukemia and chronic lymphocytic leukemia. The following ICD–10–PCS codes were established effective October 1, 2020 to identify the administration of TECARTUS®: XW23346 (Transfusion of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6) and XW24346 (Transfusion of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 6). We note that the following new ICD–10–PCS codes to describe procedures involving the administration of TECARTUS® are effective October 1, 2021: XW033M7 (Introduction of brexucabtagene autoleucel Immunotherapy into peripheral vein, percutaneous approach, new technology group 7) and XW043M7 (Introduction of brexucabtagene autoleucel Immunotherapy into central vein, percutaneous approach, new technology group 7).

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion for substantial similarity, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, TECARTUS® is the first CAR T-cell immunotherapy indicated for the treatment of r/r MCL. The applicant further asserted that it does not use a substantially similar mechanism of action. The applicant asserts the FDA concluded and approved TECARTUS® as distinct from YESCARTA® based on differences in the manufacturing process, certain product specifications and impurities, and formulation of the final products. Furthermore, the applicant stated that TECARTUS® is distinct from currently available CAR T-cell immunotherapies, namely YESCARTA® and KYMRIAH®, because neither prior CAR T-cell therapy is indicated for the treatment of patients with r/r MCL, and other differences include the manufacturing process, certain product specifications and impurities, and the final dose formulation as determined by the FDA. The applicant stated that MCL is a unique subtype of B-cell Non-Hodgkin's Lymphoma (NHL) and is distinct from DLBCL as determined by the 2016 WHO classification. The applicant stated it reviewed data from the FY 2019 100 percent MedPAR Hospital Limited Data Set to obtain a reference of currently available products used in the treatment of r/r MCL. The applicant stated that based on this analysis, available products used in the treatment of r/r MCL included: Chemotherapies, PIs, IMiDs, or BTK inhibitors. The applicant described TECARTUS® as an autologous CAR T-cell immunotherapy, which genetically modifies the patient's own T-cells to target and eliminate tumor cells for the treatment of r/r MCL and asserted that because TECARTUS® is an autologous CAR T-cell immunotherapy, it does not use the same mechanism of action as other treatments currently used to treat r/r MCL (chemotherapies, PIs, IMiDs, or BTK inhibitors).

To further note the differences between TECARTUS®'s mechanism of action and other available therapies for r/r MCL, the applicant stated that TECARTUS® represents a unique product that is customized for B-cell malignancies bearing high levels of circulating CD19-expressing tumor cells. Given these genetic modifications and differences, as previously described, the applicant described TECARTUS® as having a different mechanism of action from existing r/r MCL therapies.

The applicant stated that TECARTUS® is a distinct cellular product and is produced by a unique manufacturing process customized for B-cell malignancies characterized by circulating tumor cells and is designed to minimize the number of CD19-expressing tumor cells in the final product. The T cells in the leukapheresis product are enriched by positive selection, activated by culturing with anti-CD3 and anti-CD28 antibodies, and then transduced with a retroviral vector containing the anti-CD19 CAR gene. These engineered T cells are then propagated in culture to generate a sufficient number of cells to achieve a therapeutic effect upon infusion back into the patient. The applicant further stated that TECARTUS® has a different mechanism of action as compared to YESCARTA® given that the European Medicines Agency (EMA) deemed TECARTUS® and YESCARTA® as different products.

With respect to the second criterion for substantial similarity, whether a product is assigned to the same or a different MS–DRG, the applicant noted that CMS has established the new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapies), effective October 1, 2020, for CAR T-cell therapies. However, the applicant asserted that TECARTUS® will be uniquely identified by ICD–10–PCS codes different from those used to identify YESCARTA® and KYMRIAH®. As previously noted, under the current coding system, cases reporting the use of TECARTUS® would be coded with ICD–10–PCS codes XW23346 and XW24346, which are currently assigned to MS–DRG 018, and therefore we believe that cases reporting the use of TECARTUS® would be assigned to the same MS–DRG as existing CAR T-cell therapies.

With respect to the third criterion for substantial similarity, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that TECARTUS® is the first and only CAR T-cell immunotherapy indicated for the treatment of r/r MCL which is identified by ICD–10–CM C83.1X, mantle cell lymphoma, unspecified site. The applicant noted that the patients treated by YESCARTA® and KYMRIAH® are not assigned ICD–10–CM diagnosis code C83.1X (Mantle cell lymphoma, unspecified site), as would patients treated with TECARTUS®. As previously mentioned, the applicant described that MCL results from a malignant transformation of a B lymphocyte in the outer edge of the lymph node follicle. The applicant further stated that diffuse large b-cell lymphoma (DLBCL), which YESCARTA® and KYMRIAH® treat, is defined as a neoplasm of large B cells arranged in a diffuse pattern. The applicant described this distinction as evidence that TECARTUS® treats a different subtype of NHL, r/r MCL, as compared to other FDA approved CAR T-cell therapies. However, we noted in the proposed rule that the applicant recognized in its application that MCL and DLBCL patients share similar clinical presentation of lymphadenopathy, splenomegaly and constitutional symptoms. The applicant also noted that the disease courses for MCL and DLBCL are different given that MCL has a unique molecular pathogenesis. The applicant stated that patients with r/r MCL often present with high levels of circulating tumor cells

which are inherent to the disease [526] [527] or due to peripheral mobilization of tumor cells induced by BTK inhibitor therapy.[528] According to the applicant, MCL requires a customized CAR T-cell therapy for B-cell malignancies bearing high levels of circulating CD19-expressing tumor cells in order to provide a functional autologous cellular therapy. Unlike MCL, the presence of circulating tumor cells occurs only rarely in patients with DLBCL.[529]

With respect to the first criterion, the applicant asserted that TECARTUS® would provide a new treatment option for adult patients with r/r MCL and therefore is not substantially similar to any existing technologies. We noted that for FY 2019 (83 FR 41299), CMS approved two CD19 directed CAR T-cell therapies, YESCARTA® and KYMRIAH®, for new technology add-on payments. In regard to the mechanism of action, the applicant acknowledged that TECARTUS® is a form of CAR T-cell immunotherapy that modifies the patient's own T-cells, as are YESCARTA® and KYMRIAH®. However, the applicant asserted that the manufacturing process used by TECARTUS® makes the therapy significantly different from YESCARTA®. The applicant further asserted that its unique manufacturing process which includes a T-cell selection step for patients with MCL, ALL, and CLL is distinct from that used for the manufacture of YESCARTA® for the treatment of patients with malignancies characterized by high numbers of circulating tumor types.

Similar to our discussion of the FY 2021 application in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32636 and 32637), in the FY 2022 IPPS/LTCH PPS proposed rule, we were concerned as to whether the differences the applicant described in the manufacturing process should be considered a different mechanism of action as compared to previous CAR T-cell therapies. We noted, in their review, the FDA identified many similarities between TECARTUS® and YESCARTA® to include that, ''the YESCARTA® and KTE–X19 final products are very similar and are formulated identically. The same release testing methods are used for both products.'' [530] Further, as TECARTUS® is also a CD19-directed T-cell immunotherapy for the treatment of patients with an aggressive subtype of NHL, we continued to question whether the differences identified by the applicant would mean that TECARTUS® does not have a similar mechanism of action to existing CD19-directed CAR T-cell therapies. We sought public comment as to whether the differences the applicant described in the manufacturing process should be considered a different mechanism of action, as compared to previous CAR T-cell therapies.

With regard to the third criterion for substantial similarity, though the applicant described differences between MCL and DLBCL, the applicant also stated that patients with MCL and DLBCL share similar clinical presentation of lymphadenopathy, splenomegaly and constitutional symptoms, and they are both subtypes of NHL. We therefore questioned whether this therapy may involve the treatment of a similar type of disease when compared to existing CAR T-cell therapies.

We invited public comments on whether TECARTUS® is substantially similar to other technologies and whether TECARTUS® meets the newness criterion.

Comment: In response to CMS's concerns, a commenter stated that MCL and DLBCL differ because MCL is considered largely incurable with standard treatment approaches and has a propensity to evolve toward increasing drug resistance over time leading to shorter periods of remission. The commenter added that clinically, MCL more frequently involves the bone marrow, spleen, and extranodal sites, such as the intestinal tract, tonsils—and, in more aggressive cases, the skin, lungs, and central nervous system—in addition to enlarged lymph nodes. In contrast, the commenter stated that DLBCL more commonly involves the lymph nodes, with lower predisposition to marrow and/or organ involvement. The commenter added that in many ways, the treatment of MCL has come to more closely resemble that of multiple myeloma, where there may be limited, if any, freedom from therapy—but with MCL showing poorer outcomes. The commenter summarized that TECARTUS® couples very high response rates and remission duration without a need for any ongoing therapy.

A second commenter emphasized that MCL has important clinical features which distinguish it from DLBCL. Most importantly according to the commenter, where DLBCL is curable in up to 60% of cases, MCL remains incurable with known therapies. The commenter added that MCL cases have a median age of 65 as compared to DLBCL of 58 according to the ZUMA 1 and ZUMA 2 trials respectively. Third, the commenter stated patients with MCL often have tumor cells circulating in the peripheral blood unlik5e patients with DLBCL.

A few commenters encouraged CMS to consider assigning new technology add-on payments for new CAR T-cell therapies to ensure patient access.

Finally, a commenter stated support for CMS' desire for additional data and comment to illustrate support that TECARTUS® meets the newness criterion to support new technology add-on payment status.

Response: We appreciate the input from the commenters and the information they have highlighted, and we have taken these comments into consideration in our final decision, which is discussed later in this section.

Comment: In response to CMS' concerns the applicant submitted a public comment. The applicant stated that TECARTUS® is a distinct CAR T-cell immunotherapy approved for the treatment of r/r MCL which is different from large B-cell lymphoma and necessarily requires a different manufacturing process in order to produce a functional autologous therapy. The applicant stated that the leukapheresis material required for TECARTUS® has a more heterogeneous cell composition than that required for YESCARTA®. The applicant stated that the presence of B-lineage cells in MCL patient apheresis, unlike diffuse large B-cell lymphoma patient apheresis, necessitated the development of a CD4+ and CD8+ T-cell manufacturing selection step, which reduced the likelihood of circulating CD19 expressing tumor cells in the product and ensured a consistent efficacious and safe product for the R/R MCL patient population.

The applicant added that both the FDA and European Medicines Agency (EMA) have concluded that TECARTUS® is a unique product distinct from YESCARTA®.

In its comment, the applicant further asserted that MCL is a unique subtype of B-cell non-Hodgkin lymphoma (NHL)

[526] Argatoff LH, et al. Mantle cell lymphoma: A clinicopathologic study of 80 cases. Blood. 1997;89 (6):2067–78.

[527] Gu J, et al. Evaluation of peripheral blood involvement of mantle cell lymphoma by fluorescence in situ hybridization in comparison with immunophenotypic and morphologic findings. Mod Pathol. 2004;17 (5):553–60.

[528] Chang BY, et al. Egress of CD19(+)CD5(+) cells into peripheral blood following treatment with the Bruton tyrosine kinase inhibitor ibrutinib in mantle cell lymphoma patients. Blood. 2013;122(14):2412–24.

[529] Muringampurath-John D, et al. Characteristics and outcomes of diffuse large B-cell lymphoma presenting in leukaemic phase. B. J. Haematol. (2012) 158: 608–614.

[530] Price G, Reiser J, Salz T. CBER CMC BLA Review Memorandum, BLA #125703, TECARTUS brexucabtagene autoleucel. FDA.

and is distinct from DLBCL. The applicant added that while MCL patients may present with similar symptoms as patients with DLBCL, the conditions differ based on histopathology, genetics, clinical characteristics, treatment approaches, and clinical outcomes. The applicant asserted that the most critical distinction between MCL and DLBCL is the difference in durable complete remissions and cure with available therapies. According to the applicant, the standard of care for patients newly diagnosed with DLBCL is the immuno-chemotherapy regimen R–CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) which leads to a 'cure' in 50–60% of patients.[531] The applicant added, in contrast, although many combinations of rituximab-based immuno-chemotherapy have been examined in patients newly diagnosed with MCL, none is considered curative.[532] Further, the applicant stated that another important distinction is that patients with r/r MCL often present with high levels of circulating tumor cells which are inherent to the disease [533] [534] [535] or due to peripheral mobilization of tumor cells induced by BTK inhibitor therapy.[536] The applicant stated that MCL requires a customized CAR T-cell therapy for B-cell malignancies bearing high levels of circulating CD19-expressing tumor cells in order to provide a functional autologous cellular therapy; unlike MCL, the presence of circulating tumor cells rarely occurs in patients with DLBCL.[537] Lastly, the applicant stated that the World Health Organization has classified MCL and DLBCL as two distinct B-cell lymphoid neoplasms based on the pathogenetic differences.[538]

Response: We appreciate the additional information from the applicant regarding whether TECARTUS® is substantially similar to existing treatment options. After consideration of the public comments we received and information submitted by the applicant in its application, we agree with the applicant that TECARTUS® does not use the same or similar mechanism of action as other technologies used for the treatment of r/r MCL because it is the only CAR T-cell therapy available for the treatment of r/r MCL. Furthermore, as mentioned by the applicant, due to the differences based on histopathology, genetics, clinical characteristics, treatment approaches, and clinical outcomes we agree that this is a unique disease population as compared to that treated by other existing CAR T-cell therapies. Based on this information, we believe that TECARTUS® is not substantially similar to existing treatments and meets the newness criterion. We consider the beginning of the newness period to commence on the date TECARTUS® was approved by the FDA, July 24, 2020.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR claims data file with the FY 2019 Final Rule IPPS Impact File to identify potential cases representing patients who may be eligible for treatment using TECARTUS®.

The applicant identified claims that reported an ICD–10–CM diagnosis code of ICD–10–CM C83.1X (Mantle cell lymphoma, unspecified site). The applicant stated that claims reporting ICD–10–CM code C83.1X would not involve the use of the other two approved CAR T-cell therapies because those therapies are not used to treat this diagnosis, MCL. As such, the applicant stated that it used C83.1X to identify potential MCL cases and ICD–10–PCS codes XW033C3 and XW043C3 to identify patients receiving CAR T-cell therapy. In its analysis, the applicant identified two sets of cohorts (Primary Cohort and Sensitivity Analysis Cohort) to assess whether this therapy met the cost criterion. The ICD–10–PCS procedure codes listed in the following table were used to identify claims involving chemotherapy and the applicant noted that these were used for both cohorts.

BILLING CODE 4120–01–P

[531] Liu, Y. and Barta, SK. Diffuse large B-cell lymphoma: 2019 update on diagnosis, risk stratification, and treatment. Am. J. Hematol. (2019) 94: 604–616.

[532] Maddocks K. Update on mantle cell lymphoma. Blood. (2018) 132: 1647–1656.

[533] Argatoff LH, et al. Mantle cell lymphoma: A clinicopathologic study of 80 cases. Blood. 1997;89 (6):2067–78.

[534] Gu J., et al. Evaluation of peripheral blood involvement of mantle cell lymphoma by fluorescence in situ hybridization in comparison with immunophenotypic and morphologic findings. Mod Pathol. 2004;17 (5):553–60.

[535] Muringampurath-John D., et al. Characteristics and outcomes of diffuse large B-cell lymphoma presenting in leukaemic phase. B. J. Haematol. (2012) 158: 608–614.

[536] Chang BY., et al. Egress of CD19(+)CD5(+) cells into peripheral blood following treatment with the Bruton tyrosine kinase inhibitor ibrutinib in mantle cell lymphoma patients. Blood. 2013;122(14):2412–24.

[537] Muringampurath-John D., et al. Characteristics and outcomes of diffuse large B-cell lymphoma presenting in leukaemic phase. B.J. Haematol. (2012) 158: 608–614.

[538] Swerdlow SH., et al. The updated classification of hematological malignancies; the 2016 revision of the World Health Organization classification of lymphoid neoplasms. Blood (2016) 127 (20): 2375–2390.

ICD-10-PCS Procedure Codes Describing Chemotherapy	
ICD-10-PCS Code	**Description**
3E03002	Introduction of high-dose interleukin-2 into peripheral vein, open approach
3E03003	Introduction of low-dose interleukin-2 into peripheral vein, open approach
3E03005	Introduction of other antineoplastic into peripheral vein, open approach
3E03302	Introduction of high-dose interleukin-2 into peripheral vein, percutaneous approach
3E03303	Introduction of low-dose interleukin-2 into peripheral vein, percutaneous approach
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04002	Introduction of high-dose interleukin-2 into central vein, open approach
3E04003	Introduction of low-dose interleukin-2 into central vein, open approach
3E04005	Introduction of other antineoplastic into central vein, open approach
3E04302	Introduction of high-dose interleukin-2 into central vein, percutaneous approach
3E04303	Introduction of low-dose interleukin-2 into central vein, percutaneous approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

The applicant identified two cohorts for these analyses and used two CCRs to account for the cost of their technology. The Primary Cohort included cases with an ICD–10–CM primary diagnosis of MCL, at least one procedure code indicating receipt of chemotherapy, and no ICD–10–PCS procedure codes indicating CAR T-cell therapy. The applicant believed the Primary Cohort most closely aligned with the characteristics and health of r/r MCL patients who would receive TECARTUS® given that this cohort includes patients with far advanced disease (comparable to the ZUMA–2 study, as discussed later in this section). The Sensitivity Analysis Cohort included patients with the ICD–10–CM principal or secondary diagnosis of MCL, at least one procedure code indicating receipt of chemotherapy, and no ICD–10–PCS procedure codes indicating CAR T-cell therapy. For each cohort, the applicant performed two sub-analyses that varied the CCR used to calculate TECARTUS® charges: (1) The national pharmacy CCR of 0.187; and (2) the applicant calculated CAR T-cell CCR of 0.314.

According to the applicant, based on the primary diagnosis code and the presence of chemotherapy, these cases signify that the primary reason for hospitalization was treatment of the patient's MCL, including the complications of their advancing disease and chemotherapy-related complications, and resulted in charges and longer lengths of stay believed to be most reflective of the r/r MCL population that is treated by TECARTUS. The applicant added that this group of MCL cases with MCL as a primary diagnosis most closely compares with the characteristics and health resource utilization of r/r MCL patients that will receive TECARTUS. Furthermore, the applicant stated that the cases in the Primary Cohort had higher charges across all categories than the cases with MCL as a secondary diagnosis. The cases with MCL as a primary diagnosis are according to the applicant more reflective of the r/r MCL population as those cases were more likely being treated for the complications of their advancing disease and chemotherapy-related complications. The average length of stay for hospitalizations in the Primary Cohort was 15.1 days. Lastly, in explaining why CAR T-cell MCL cases from FY 2019 were excluded from the cost analysis, the applicant stated that they could not identify specific charges for CAR T-cell therapy, no individual revenue center had charges similar to those expected for CAR T-cell therapy, and there were no CAR T-cell therapy products approved for the treatment of MCL in FY 2019.

The applicant stated that to estimate the CAR T-cell CCR, they obtained the MS–DRG 018 arithmetic mean charge in the AOR/BOR FY 2021 Proposed Rule File released by CMS ($1,387,946). The applicant subtracted non-drug charges for TECARTUS of $201,610 (based on the TECARTUS FY 2021 new technology add-on payment application) from the total arithmetic mean charge to estimate CAR T-cell charges (approximately $1,186,336). The applicant then divided a WAC of CAR T-cell therapy of $373,000 by the estimated CAR T-cell charges to estimate a charge-to-cost ratio of 0.314 (CCR = 373,000/1,186,336).

The claim search conducted by the applicant resulted in 267 claims in the Primary Cohort, mapped to 13 MS–DRGs, and 1,100 claims in the Sensitivity Analysis Cohort, mapped to 59 MS–DRGs using the FY 2019 MedPAR Hospital LDS based on the requirements for each cohort outlined by the applicant. The applicant stated that because TECARTUS cases are mapped to MS–DRG 018, the cost criterion analysis utilized the threshold for MS–DRG 018 for all MS–DRGs included in each cohort rather than the MS–DRG specific threshold. The applicant determined an average unstandardized case weighted charge per case of $1,251,126 for the Primary cohort and $1,251,126 for the Sensitivity Analysis Cohort.

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MS-DRGs in Primary Cohort	
MS-DRG	**Description**
840	Lymphoma & Non-Acute Leukemia w MCC
841	Lymphoma & Non-Acute Leukemia w CC
016	Autologous Bone Marrow Transplant w CC/MCC Or T-Cell Immunotherapy
823	Lymphoma & Non-Acute Leukemia w Other Proc w MCC
842	Lymphoma & Non-Acute Leukemia w/o CC/MCC
824	Lymphoma & Non-Acute Leukemia w Other Proc w CC
014	Allogeneic Bone Marrow Transplant
017	Autologous Bone Marrow Transplant w/o CC/MCC
820	Lymphoma & Leukemia w Major O.R. Procedure w MCC
003	Ecmo Or Trach w Mv >96 Hrs or Pdx Exc Face, Mouth & Neck w Maj O.R.
004	Trach w Mv >96 Hrs or Pdx Exc Face, Mouth & Neck w/o Maj O.R.
821	Lymphoma & Leukemia w Major O.R. Procedure w CC
825	Lymphoma & Non-Acute Leukemia w Other Proc w/o CC/MCC

MS-DRGs in Sensitivity Analysis Cohort	
MS-DRG	**Description**
847	Chemotherapy w/o Acute Leukemia As Secondary Diagnosis w CC
846	Chemotherapy w/o Acute Leukemia As Secondary Diagnosis w MCC
840	Lymphoma & Non-Acute Leukemia w MCC
841	Lymphoma & Non-Acute Leukemia w CC
016	Autologous Bone Marrow Transplant w CC/MCC or T-Cell Immunotherapy
823	Lymphoma & Non-Acute Leukemia w Other Proc w MCC
842	Lymphoma & Non-Acute Leukemia w/o CC/MCC
824	Lymphoma & Non-Acute Leukemia w Other Proc w CC
829	Myeloproliferative Disorders or Poorly Differentiated Neoplasms w Other Procedure w CC/MCC

MS-DRGs in Sensitivity Analysis Cohort	
MS-DRG	**Description**
014	Allogeneic Bone Marrow Transplant
682	Renal Failure w MCC
871	Septicemia or Severe Sepsis w/o Mv >96 Hours w MCC
017	Autologous Bone Marrow Transplant w/o CC/MCC
838	Chemo w Acute Leukemia As Sdx w CC Or High Dose Chemo Agent
820	Lymphoma & Leukemia w Major O.R. Procedure w MCC
808	Major Hematol/Immun Diag Exc Sickle Cell Crisis & Coagul w MCC
809	Major Hematol/Immun Diag Exc Sickle Cell Crisis & Coagul w CC
683	Renal Failure w CC
004	Trach w Mv >96 Hrs or Pdx Exc Face, Mouth & Neck w/o Maj O.R.
864	Fever and Inflammatory Conditions
054	Nervous System Neoplasms w MCC
948	Signs & Symptoms w/o MCC
003	Ecmo or Trach w Mv >96 Hrs or Pdx Exc Face, Mouth & Neck w Maj O.R.
825	Lymphoma & Non-Acute Leukemia w Other Proc w/o CC/MCC
175	Pulmonary Embolism w MCC or Acute Cor Pulmonale
813	Coagulation Disorders
853	Infectious & Parasitic Diseases w O.R. Procedure w MCC
189	Pulmonary Edema & Respiratory Failure
603	Cellulitis w/o MCC
180	Respiratory Neoplasms w MCC
870	Septicemia or Severe Sepsis w Mv >96 Hours
394	Other Digestive System Diagnoses w CC
312	Syncope & Collapse
821	Lymphoma & Leukemia w Major O.R. Procedure w CC
674	Other Kidney & Urinary Tract Procedures w CC
837	Chemo w Acute Leukemia as Sdx or w High Dose Chemo Agent w MCC
668	Transurethral Procedures w MCC
091	Other Disorders of Nervous System w MCC
543	Pathological Fractures & Musculoskelet & Conn Tiss Malig w CC
294	Deep Vein Thrombophlebitis w CC/MCC

854	Infectious & Parasitic Diseases w O.R. Procedure w CC
314	Other Circulatory System Diagnoses w MCC
606	Minor Skin Disorders w MCC
641	Misc Disorders of Nutrition, Metabolism, Fluids/Electrolytes w/o MCC
392	Esophagitis, Gastroent & Misc Digest Disorders w/o MCC
827	Myeloprolif Disord or Poorly Diff Neopl w Maj O.R. Proc w CC
253	Other Vascular Procedures w CC
834	Acute Leukemia w/o Major O.R. Procedure w MCC
552	Medical Back Problems w/o MCC
673	Other Kidney & Urinary Tract Procedures w MCC
393	Other Digestive System Diagnoses w MCC
371	Major Gastrointestinal Disorders & Peritoneal Infections w MCC
315	Other Circulatory System Diagnoses w CC
607	Minor Skin Disorders w/o MCC
205	Other Respiratory System Diagnoses w MCC
602	Cellulitis w MCC
025	Craniotomy & Endovascular Intracranial Procedures w MCC
811	Red Blood Cell Disorders w MCC
270	Other Major Cardiovascular Procedures w MCC
071	Nonspecific Cerebrovascular Disorders w CC
273	Percutaneous Intracardiac Procedures w MCC
826	Myeloprolif Disord or Poorly Diff Neopl w Maj O.R. Proc w MCC
193	Simple Pneumonia & Pleurisy w MCC
867	Other Infectious & Parasitic Diseases Diagnoses w MCC
191	Chronic Obstructive Pulmonary Disease w CC
982	Extensive O.R. Procedure Unrelated to Principal Diagnosis w CC
391	Esophagitis, Gastroent & Misc Digest Disorders w MCC
699	Other Kidney & Urinary Tract Diagnoses w CC
309	Cardiac Arrhythmia & Conduction Disorders w CC
100	Seizures w MCC
662	Minor Bladder Procedures w MCC
186	Pleural Effusion w MCC

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The applicant then removed charges for the prior technology. The applicant stated that the cases representing patients who had received

chemotherapy, as reflected by the Medicare claims data, would generally not receive both chemotherapy and TECARTUS® as an inpatient because conditioning chemotherapy would be administered in the outpatient setting before the patient would be admitted for TECARTUS® infusion and monitoring. Otherwise, the applicant asserted that patients receiving TECARTUS® would be expected to incur similar charges to those cases in the Medicare claims data for patients with a primary diagnosis of MCL and receiving chemotherapy (Primary Cohort). In its analysis, the applicant noted that in the FY 2019 MedPAR Hospital LDS, charges for chemotherapy drugs were grouped with charges for oncology, diagnostic radiology, therapeutic radiology, nuclear medicine, CT scans, and other imaging services. The applicant believed that removing all radiology charges would understate the cost of adverse event (AE) clinical management for TECARTUS® patients needed. The applicant found that when using data from the Q4 2017 and Q1 Q3 2018 Standard Analytic files and comparing total chemotherapy charges to total radiology charges, 2 percent of radiology charges were chemotherapy charges, on average. Therefore, instead of removing all radiology charges, the applicant excluded 2 percent of the radiology charge amount to capture the effect of removing chemotherapy pharmacy charges.

The applicant then standardized the charges and applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). For the Primary and Sensitivity cohorts, the applicant performed two sub-analyses that varied the CCR used to calculate TECARTUS® charges: (1) Using the national pharmacy CCR (0.187); and (2) using the CAR T-cell CCR (0.314).

The applicant stated that when comparing the Primary Cohort to the MS–DRG 018 average case-weighed threshold amount (based on the FY 2021 IPPS/LTCH PPS final rule) and using the national pharmacy CCR, the final inflated average case-weighted standardized charge per case of $2,207,969 exceeded the average case-weighted threshold amount of $1,251,126 by $956,843. When using the CAR T-cell CCR, the final inflated average case-weighted standardized charge per case of $1,399,653 exceeded the average case-weighted threshold amount of $1,251,126 by $148,527. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

When conducting the same review to assess cost for the Sensitivity Analysis Cohort, the applicant noted that the sensitivity analysis cohort also meets the cost criterion when compared to the MS–DRG 018 average case-weighted threshold amount (based on the FY 2021 IPPS/LTCH PPS data file thresholds for FY 2022). As reported by the applicant, when using the national pharmacy CCR in the sensitivity analysis cohort the final inflated average case-weighted standardized charge per case of $2,142,149 exceeded the average case-weighted threshold amount of $1,251,126 by $891,023. When using the CAR T-cell CCR in the sensitivity analysis cohort, the final inflated average case-weighted standardized charge per case of $1,333,833 exceeded the average case-weighted threshold amount of $1,251,126 by $82,707. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

Because the final inflated average case-weighted standardized charge per case for both the Primary Cohort and the Sensitivity Analysis Cohort exceeds the average case-weighted threshold amount for MS–DRG 018, the applicant maintained that the technology meets the cost criterion.

As noted in previous discussions, the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy. Therefore, with regard to the use of this data for purposes of calculating a CAR T-cell CCR we stated we were uncertain how representative this data is for use in the applicant's cost analyses given this potential for variability.

We stated in the proposed rule that we continue to be interested in public comments regarding the eligibility of CAR T-cell technologies for new technology add-on payments when assigned to MS–DRG 018. As we have noted in prior rulemaking with regard to the CAR T-cell therapies (83 FR 41172 and 85 FR 58603 through 58608), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act.

We invited public comment on whether TECARTUS® meets the cost criterion.

Comment: We received a comment from MEDPAC which addressed the cost criterion in general as it relates to CAR T-cell therapies.

Response: Please refer to the response in the BREYANZI® application in section II.F.X.c. of the preamble of this final rule for a detailed discussion of this issue.

Comment: We received multiple comments in response to our concern for CAR T-cell therapy, the MS–DRG 018 assignment, and new technology add-on payment eligibility.

Response: For a complete discussion of these comments and our response, please see the BREYANZI® application in section II.F.X.c. of the preamble of this final rule.

Comment: A commenter stated support for CMS' desire for additional data and comment to illustrate support that TECARTUS® meets the cost criterion to support new technology add-on payment status.

Response: We appreciate the input from the commenter and have taken this comment into consideration in determining whether TECARTUS® meets the cost criterion.

Comment: A commenter, the applicant, maintained that the cost analyses demonstrate that TECARTUS® meets the cost criterion. In response to CMS' concern regarding the representativeness of the cost data for TECARTUS® based on the CAR T-cell CCR, the applicant stated it appreciates CMS' concern regarding the ''representativeness'' of the estimated CAR T-cell CCR and agree that CCRs are likely to vary widely for CAR T-cell therapies. The applicant stated that while it is standard to use the pharmacy CCR to convert drug costs to charges and CMS has accepted the use of this CCR in the past for cost criterion analyses, CAR T-cell therapies, including TECARTUS®, are new and novel therapeutics, and they were concerned that CMS would question the applicability of the pharmacy CCR for purposes of demonstrating that TECARTUS® met the cost criterion. Therefore, the applicant created two sets of analyses to demonstrate that TECARTUS® meets the cost criterion, using both the national pharmacy CCR and an estimate of the CAR T-cell CCR. Furthermore, the applicant stated that the CAR T-cell therapy CCR of 0.314 is similar to the CAR T-cell therapy CCR of 0.295 used by other applicants for CAR T-cell therapy for FY 2022 new technology add-on payment applications as summarized in the FY 2022 CMS IPPS/LTCH PPS proposed rule: BREYANZI (86 FR 25231), ciltacabtagene autoleucel (86 FR 225237), and idecabtagene vicleucel (86 FR 225258). Lastly, the applicant

commented TECARTUS® would also have met the cost criterion if the 0.295 CCR had been used in their analyses.

The applicant stated that in the proposed rule, CMS solicited comments on whether with the creation of MS–DRG 018 there may no longer be a need for CAR T-cell products to receive a new technology add-on payment. The applicant stated their belief that the creation of MS–DRG 018 does not alter the new technology add-on payment eligibility of future CAR T-cell products. The applicant stated the language under section 1886(d)(5)(K)(ix) is long-standing and has never before been interpreted as potentially imposing a blanket exclusion from new technology add-on payment eligibility. The applicant asserted that instead, CMS has historically operationalized section 1886(d)(5)(K)(ix) by establishing the new technology add-on payment criteria of newness, cost, and substantial clinical improvement. In particular, the applicant contends that CMS has viewed its evaluation under the cost criterion as directly satisfying the agency's obligation under section 1886(d)(5)(K)(ix) of the Act. The applicant stated, in 2005 rulemaking where the agency first recognized the addition of section 1886(d)(5)(K)(ix) of the Act, as amended by section 503(c) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[539] CMS stated that ''at the time an application for new technology add-on payments is submitted, the DRGs associated with the new technology are identified.'' [540] The applicant added CMS went on to state that it ''only determine[s] that a new DRG assignment is necessary or a new technology add-on payment is appropriate when the reimbursement under these currently assigned DRGs is not adequate for this new technology.'' The applicant asserted that the current MS–DRG assignment for a case using a new CAR T-cell product would be MS–DRG 018 and CMS should follow the same approach for a new CAR T-cell product as for all other products applying for a new technology add-on payment: Determine whether the current MS–DRG assignment is inadequate and if so, either make a new MS–DRG assignment or provide for a new technology add-on payment. The applicant added if the fact that the current MS–DRG assignment takes into consideration the use of a particular therapy would disqualify new products from being eligible for a new technology add-on payment, then many more products in addition to CAR T-cell would be affected (for example, new pacemakers and the MS–DRGs 242–244 to which pacemaker cases are assigned).

Response: We appreciate the information provided by the applicant in their comment in regard to their calculation of a CAR T-cell CCR. As we stated in section E.2.b. of this rule, we continue to believe that it is premature to make structural changes to the IPPS at this time to pay for CAR T-cell therapies (78 FR 58453). As we gain more experience paying for these therapies under the IPPS, we may consider these comments to inform future rulemaking. However, we appreciate the thoughtfulness used by the applicant to provide as clear as possible a description of CAR T-cell therapy cost calculations. We appreciate the usage of multiple cost analyses, such as varying the CCR used to inflate cost to charges, which potentially allowed for a more conservative markup.

After consideration of the public comments we received and based on the information included in the applicant's new technology add-on payment application, we believe that the TECARTUS® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that TECARTUS® represents a new treatment option for an adult patient population unresponsive to, or ineligible for, currently available treatments. The applicant also believes that the use of TECARTUS® significantly improves clinical outcomes for a patient with r/r MCL as compared to currently available therapies, including BTK inhibitors. The applicant stated that TECARTUS® provides access to a treatment option for patients with r/r MCL who have not been responsive to first line or second line therapies. The applicant provided further detail regarding these assertions, referencing the results of a Phase 2 study (Zuma–2) and historical and meta analyses, which are summarized in this section of this rule.

According to the applicant, because no effective standard therapy for subjects with r/r MCL who have progressed following a prior BTK inhibitor therapy exists, ZUMA–2 lacked a comparison arm. The applicant described how a historical control was the only ethical and feasible study design for patients with r/r MCL who had not responded to the most promising therapies available, including BTK inhibitors. Therefore, the historical control was identified from prior studies identified in a meta-analysis of six studies, which included two studies by Martin et al., (2016) and Cheah et al., (2015), and covered 255 subjects. The ORRs in these six studies ranged from 20%–42% with the applicant identifying 26%[541] and 32%[542] for use as their comparator.

According to the Martin et al. (2016) retrospective cohort study referenced by the applicant, the investigators reported best response rate (RR) to ibrutinib was 55% (43% partial response [PR], 12% complete response [CR]), with 35% of patients having a best response of progressive disease. But among patients who received subsequent therapy, local clinicians reported that 13 patients (19%) achieved PR, and 5 (7%) achieved CR. The median overall survival (OS) following cessation of ibrutinib was 2.9 months (95% confidence interval [CI], 1.6–4.9). Of the 104 patients with data available, 73 underwent at least one additional line of currently available treatment after stopping ibrutinib with a median OS of 5.8 months (95% confidence interval [CI], 3.7–10.4).[543]

A second retrospective study by Cheah et al. identified 42 (54%) who had discontinued therapy of 78 patients with MCL who had been treated at MD Anderson Cancer Center between 2011 and 2014.[544] All 42 patients had received ibrutinib with a median number of cycles of 6.5 (range 1–43). Twenty-eight patients (67%) had disease progression as the main reason for therapy discontinuation. Of the 31 patients who experienced disease progression following ibrutinib and underwent salvage therapy, the overall objective response rate (ORR) and complete response rate (CRR) was 32% and 19%, respectively. After a median follow-up of 10.7 (range 2.4–38.9) months from discontinuation of ibrutinib, the median OS among patients with disease progression was 8.4 months and the estimated one-year OS was 22.1% (95% CI 8.3% to 40.2%).

The applicant summarized further studies that featured BTK therapy. Dreyling et al. and Epperla et al. identified ORRs of 20% and 42% respectively while Wang et al. identified an ORR of 29%, CR rate of 14%, and PR rate of 15% and Jaln et al. identified an

[539] Public Law 108–173 (Dec. 8, 2003).

[540] 70 FR 47278, 47343 (Aug. 12, 2005).

[541] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[542] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. Ann Oncol. 2015;26(6):1175–9.

[543] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[544] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. Ann Oncol. 2015;26(6):1175–9.

ORR of 29%, CR rate of 14%, and PR rate of 15%.[545] [546] [547] [548]

To evaluate the effectiveness of TECARTUS®, the applicant noted it used an ORR comparison of 25%, which was derived from two aforementioned studies (Martin et al. and Cheah et al.) with patients with r/r MCL who progressed on the most predominantly prescribed BTK inhibitor, ibrutinib. The results of these two studies showed a median OS of 5.8 months after receiving at least 1 additional line of currently available therapy to treat r/r MCL. Those who did not receive salvage therapy had a median OS of 0.8 months.[549]

According to the applicant, the ZUMA–2 study of TECARTUS® is the only pivotal study of CAR T-cell therapy for r/r MCL. ZUMA–2 is a multicenter, open label, Phase 2 study which evaluated the safety and efficacy of TECARTUS® in patients with r/r MCL that relapsed or are refractory to prior therapy, including BTK inhibitors. The primary endpoint compared the ORR from the study to the ORR 25% historical control at a one-sided alpha level of 0.025. The applicant stated that ZUMA–2 was not designed to compare the efficacy and safety of TECARTUS to BTK inhibitors, and the results of ZUMA–2 are not intended to indicate that TECARTUS should definitively be utilized to replace any existing therapies. Participants were required to have received prior treatment for MCL, no more than five prior regimens, which must have included anthracycline (or bendamustine containing chemotherapy), an anti-CD20 monoclonal antibody and BTK inhibitor. The ZUMA–2 study included 68 subjects treated with TECARTUS® out of 75 patients enrolled. The safety analysis included a review of all 68 subjects, with the primary analysis of efficacy reviewing the first 60 subjects treated with TECARTUS®. ZUMA–2 was conducted at 20 sites in the United States and Europe. Of the 60 subjects in the primary analysis set, 59 were from U.S. sites. Of the 68 subjects in the safety analysis set, 62 were from U.S. sites. Among the 68 subjects, the median age was 65 years (range 38–79) and 57 subjects (84%) were male. Additionally, 58 subjects (85%) had stage IV disease. The sample had a median of 3 prior therapies with 55 (81%) having received ≥3 prior therapies. In addition, 43% had relapsed after a prior autologous stem cell transplant (ASCT); the remaining subjects had either relapsed after or were refractory to their last therapy for MCL.

The applicant asserted that the use of TECARTUS® significantly improves clinical outcomes for a patient population as compared to currently available treatments. The applicant contended that ibrutinib, a BTK inhibitor, is the most common third-line therapy used for patients with r/r MCL [550] [551] and has been shown to offer improvements over other chemotherapy-based regimens for r/r MCL patients. The applicant also referenced a more selective BTK inhibitor, acalabrutinib, which was approved in the US for the treatment of patients with r/r MCL.[552] [553] In registrational trials, the ORR and CRR were 66% and 17%, respectively for ibrutinib, and 81% and 40%, respectively, for acalabrutinib.[554] [555] The applicant contended that primary and secondary resistance to BTK inhibitors [556] is common, and subsequent therapies currently available are minimally effective.[557] [558] [559]

Among the 68 patients treated in the ZUMA–2 study, the primary efficacy analysis was conducted after 60 patients had been enrolled, treated, and evaluated for response for six months after the week four disease assessment. Based on the primary analysis of the 60 subjects included in the ZUMA–2 study, there was an ORR of 93% after a single dose of TECARTUS® (56 of 60 subjects with a 95% CI of 83.8%, 98.2%). The applicant reported that the complete response rate was 67% (40 of 60 subjects with a 95% CI of 53.3%, 78.3%). The applicant noted the ORR of 93% and CR 67% were observed across age groups (94% ages ≥65; 93% ages <65 and, of the 40 subjects achieving CR, 22 subjects were aged ≥65 and 18 were aged <65). The applicant highlighted that the ORR of 93% was significantly higher than the prespecified historical control rate of 25%. Furthermore, the applicant noted that among the 42 subjects who initially had a partial response (PR) or stable disease (SD), 24 subjects (57%) went on to achieve a CR after a median of 2.2 months (range: 1.8 to 8.3 months). Twenty-one subjects converted from PR to CR, and 3 subjects converted from stable disease (SD) to CR.

According to the applicant, the median DOR was not reached with a median follow-up time for DOR of 8.6 months (95% CI: 7.8, 19.6 months) with a median study follow-up of 12.3 months; this result was consistent across age groups. Kaplan-Meier estimates of the progression free survival (PFS) rates at 6 months and 12 months were 77.0% and 60.9%, respectively, and the median PFS was not reached at the median potential follow-up of 12.3 months. Additionally, 57% of all patients and 78% of patients with a CR remained in remission (results consistent across age groups). Furthermore, as reported by the applicant, among the first 28 subjects studied as part of the interim analysis, 43% remained in continued remission without additional therapy at the follow-up period of 27 months (range, 25.3–32.3).

The applicant also conducted an additional analysis of OS among the first 28 subjects (ZUMA–2 interim analysis) who were treated with TECARTUS® and had a potential follow-up of ≥24 months. Among these subjects, the OS rate estimate at 24 months was 67.9% and the median OS was not reached. In comparison, the Cheah et al. (2015) post-ibrutinib salvage therapy study reported a lower one-year survival rate of 22%. Additionally, among the subjects in CR at month 3 who had the opportunity to

[545] Dreyling M, et al. Ibrutinib versus temsirolimus in patients with relapsed or refractory mantle-cell lymphoma: An international, randomised, open-label, phase 3 study. Lancet. 2016;387(10020):770–8.

[546] Epperla N, et al. Predictive factors and outcomes for ibrutinib therapy in relapsed/refractory mantle cell lymphoma—a ''real world'' study. Hematological Oncology. 2017:1–8.

[547] Wang M, et al. Observational study of lenalidomide in patients with mantle cell lymphoma who relapsed/progressed after or were refractory/intolerant to ibrutinib (MCL–004). J Hematol Oncol. 2017;10:171.

[548] Jain P, et al. Long-term outcomes and mutation profiling of patients with mantle cell lymphoma (MCL) who discontinued ibrutinib. Br J Haematol. 2018a;183:578–87.

[549] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[550] Campo E, Rule S. Mantle cell lymphoma: Evolving management strategies. Blood. 2015;125(1):48–55.

[551] Vose JM. Mantle cell lymphoma: 2017 update on diagnosis, risk-stratification, and clinical management. Am J Hematol. 2017;92(8):806–813.

[552] Kantar Health. CancerMPact® United States. September 2018, v1.2.

[553] Vose JM. Mantle cell lymphoma: 2017 update on diagnosis, risk-stratification, and clinical management. Am J Hematol. 2017;92(8):806–813.

[554] Ibrutinib USPI. Available from: *https://www.imbruvica.com/docs/librariesprovider7/default-document-library/prescribing_information.pdf*.

[555] Acalabrutinib USPI. Available from: *https://www.azpicentral.com/calquence/calquence.pdf#page=1*.

[556] Rule S, et al. Median 3.5-year follow-up of ibrutinib treatment in patients with relapsed/refractory Mantle Cell Lymphoma: a pooled analysis. *Blood* Dec. 2017;130(Suppl 1):151.

[557] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. *Ann Oncol.* 2015;26(6):1175–9.

[558] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. *Blood.* 2016;127 (12):1559–63.

[559] DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials.* 1986;7(3):177–88.

be followed to month 12, 90% remained in CR at month 12. The applicant contended that this statistic showcased that early responses to TECARTUS® are likely indicative of long-term remission after the single infusion of TECARTUS®. Furthermore, the applicant suggested that a substantial number of patients with r/r MCL treated with TECARTUS® will achieve a CR, and that this suggests these patients will likely experience a long-term remission after a single infusion of TECARTUS®. The applicant also noted that these results were consistent across age groups at the time of the primary data analysis cut-off (July 24, 2019). By contrast, the applicant noted that patients with r/r MCL who had prior BTK inhibitor treatment had CR rates ranging from 7–22%. Additionally, the applicant noted that the majority of patients on BTK inhibitor treatment go on to have progressive disease given that the responses achieved with currently available salvage therapies are short lived and have a DOR ranging from 3 to 5.8 months.[560] [561] [562] [563]

With regard to the safety of TECARTUS®, the applicant argued that the ZUMA–2 study demonstrated a positive benefit-risk of TECARTUS® over the current therapy options for patients with r/r MCL. The applicant stated that the toxicity profile that is associated with TECARTUS® therapy can be managed based upon established guidance. The applicant further stated that the risk evaluation and mitigation strategies (REMS) program will ensure that hospitals providing TECARTUS® therapy are certified so that all who prescribe, dispense, or administer TECARTUS® are aware of how to manage the risk of cytokine release syndrome (CRS) and neurologic events. However, the applicant notes that patients who were ≥65 years old showed a trend toward a higher incidence of Grade 3 or higher CRS compared to those ≤65 years old. (21% versus 7%). Additionally, all subjects in the ZUMA–2 primary analysis had at least one adverse event (AE), 99% of subjects had at least one AE that was Grade 3 or higher, and 68% of subjects had at least one serious adverse event (SAE). Among all 68 treated patients, the most common Grade 3 or higher AEs were anemia (51%), neutropenia (53%), and leukopenia (41%). Furthermore, CRS occurred in 62 subjects (91%) in the ZUMA–2 safety analysis. Of these, 10 subjects (15%) had Grade 3 CRS or higher. No subject had Grade 5 CRS, according to the applicant. Furthermore, according the applicant, the most common CRS symptoms of any grade were pyrexia, hypotension, and hypoxia. The most common Grade 3 or higher CRS symptoms were hypotension (35 subjects, 51%), hypoxia (23 subjects, 34%), and pyrexia (62 subjects, 91%). No patient in the ZUMA–2 study treated with TECARTUS® died from CRS.

The applicant mentioned that 43 of the 68 patients (63%) in the ZUMA–2 study also experienced forms of neurologic events. Of these, 15 subjects (22%) had a worst Grade 3 neurologic event, and 6 subjects (9%) had a worst Grade 4 neurologic event. Twenty-two subjects (32%) had serious neurologic events, however, the applicant noted no subject had a Grade 5 neurologic event. The most common neurologic events of any grade were encephalopathy (21 subjects, 31%), confusional state (14 subjects, 21%), and tremor (24 subjects, 35%). Compared with subjects who were <65 years of age, subjects who were ≥65 years of age showed a trend toward a higher incidence of Grade 3 or higher neurologic events (36% versus 24%). The applicant noted that these neurologic events resolved for all but 6 subjects and that among those whose neurologic events had resolved, the median duration was 12 days. Additionally, no patient died from neurologic events.

In response to CMS's concern as discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32646 through 32647) regarding the generalizability of the findings from ZUMA–2 to the general Medicare population, the applicant stated that the ZUMA–2 study sample is representative of the Medicare population. The applicant stated that 57% of the sample were 65 to 79 years of age, and that MCL predominantly affects older adults, with a median age at diagnosis ranging from 65 to 73.[564] [565] The applicant asserted that the advanced disease characteristics, including Stage IV disease in 85%, bone marrow involvement in 54%, and splenic involvement in 34%, closely align with those observed in the general MCL population where newly diagnosed and previously untreated patients present with stage III/IV disease and commonly exhibit splenomegaly and bone marrow infiltration.[566] The applicant added that the key baseline characteristics of the ZUMA–2 population mirror the r/r MCL Medicare population refractory to BTK inhibitors, including age of study subjects and stage of disease at study initiation. Overall, ZUMA–2 primary results showed that at the time of the analysis cutoff (July 2019), 16 of 68 subjects (24%) had died; 4 deaths occurred >30 days through 3 months after infusion of TECARTUS® and 12 deaths occurred ≥3 months after infusion of TECARTUS®. Fourteen of the 16 subjects died as a result of progressive disease and two of the 16 subjects died due to AEs (Grade 5 AE of staphylococcal bacteremia and Grade 5 AE of organizing pneumonia).

Based on the information provided by the applicant, we had several concerns with regard to the substantial clinical improvement criterion. As we noted in the FY 2021 IPPS/LTCH PPS proposed rule, the combined sample size from the literature search and ZUMA–2 study performed by the applicant is relatively small. While the applicant stated that it closely communicated with FDA in the development of the ZUMA–2 study, including in the development of the sample size, we questioned whether the ZUMA–2 study results would support a determination of substantial clinical improvement given the small sample size. Although the applicant's analysis of the ZUMA–2 study concluded that TECARTUS® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we questioned whether the sample size and research presented in this application support extrapolating these results across the Medicare population.

Relatedly, we had concerns regarding the potential for selection bias and its effects on results from the ZUMA–2 study. Seventy-four patients were enrolled in the trial and underwent leukapheresis, of which TECARTUS® was successfully manufactured for 71

[560] Kochenderfer JN, et al. Lymphoma Remissions Caused by Anti-CD19 Chimeric Antigen Receptor T Cells Are Associated With High Serum Interleukin-15 Levels. *J Clin Oncol.* 2017a;35(16):1803–13.

[561] Kochenderfer JN, et al. Long-Duration Complete Remissions of Diffuse Large B Cell Lymphoma after Anti-CD19 Chimeric Antigen Receptor T Cell Therapy. *Mol Ther.* 2017b;25(10):2245–53.

[562] Gupta S, et al. Recommendations for the design, optimization, and qualification of cell-based assays used for the detection of neutralizing antibody responses elicited to biological therapeutics. *Journal of Immunological Methods.* 2007;321(1–2):1–18.

[563] Davila ML, et al. Efficacy and toxicity management of 19–28z CAR T cell therapy in B cell acute lymphoblastic leukemia. *Sci Transl Med.* 2014;6(224):224ra25.

[564] Smith A, et al. Lymphoma incidence, survival and prevalence 2004–2014: Sub-type analyses from the UK's Haematological Malignancy Research Network. Br J Cancer. 2015;112(9):1575–84.

[565] Romaguera JE, et al. High rate of durable remissions after treatment of newly diagnosed aggressive mantle-cell lymphoma with rituximab plus hyper-CVAD alternating with rituximab plus high-dose methotrexate and cytarabine. J Clin Oncol. 2005;23(28):7013–23.

[566] McKay P, et al. Guidelines for investigation and management of mantle cell lymphoma. Br J Haematol. (2012) 159, 405–426.

(96%) and administered for 68 (92%).[567] According to the authors, the primary efficacy analysis was performed among the 60 first treated patients who had at least 7 months of follow up. We also noted that the reported ORR among the first 60 is 93% (95% CI 84–98) and the ORR among all 74 patients enrolled is 85%. We had concerns, given the small sample, about the potential effects of selection bias and of patients being selected out of a study on the results of ZUMA–2, which forms the keystone of the applicant's assertions regarding substantial clinical improvement. Further, some research suggests that trials stopped early for benefit overestimate treatment effects [568] [569] [570] and that formal stopping rules do not reduce this bias, particularly in samples less than 500 events or cases.[571] Given the lack of confidence intervals around the ORR among all 74 patients and the potential for the overestimation of treatment effects, we stated it was unclear whether there was sufficient information to determine a substantial clinical improvement.

As noted in the FY 2021 IPPS/LTCH PPS proposed rule, there had not been a direct study completed comparing outcomes of patients with r/r MCL treatment with TECARTUS® and BTK inhibitors. According to the applicant, ZUMA–2 remains the only study to evaluate patient outcomes after receiving TECARTUS® for the treatment of r/r MCL, but this study did not include a direct comparison to other existing therapies for r/r MCL. Despite there being no standard of second-line care for r/r MCL patients that failed on previous therapies, according to the applicant, a BTK inhibitor reflects the best currently available therapy for treating r/r MCL.[572]

The applicant's assertions of substantial clinical improvement are based on the ZUMA–2 trial that uses a historical control ORR of 25%. Given that the ORR in the provided literature review of six articles ranges from 20%–42%, and that, according to the applicant, two specific articles were used to develop the pre-specified historical control rate (26% [573] and 32% [574] respectively),we stated it was unclear whether the historical control is appropriate or representative of r/r MCL patients. Furthermore, given that the applicant states that ZUMA–2 was not designed to compare efficacy and safety of TECARTUS® to BTK inhibitors, we were uncertain whether it would support a determination of substantial clinical improvement.

We stated that, as noted in the FY 2021 IPPS/LTCH PPS proposed rule, a longer-term analysis of this population is not available to evaluate the overall survival and mortality data. We noted that the applicant did conduct an additional analysis of OS among the first 28 subjects (ZUMA–2 interim analysis) which showed an OS rate estimate at 24 months of 67.9% while the median OS was not reached. Additionally, the applicant referenced that all subjects in the ZUMA–2 primary analysis had at least 1 adverse event, and that throughout the course of the ZUMA–2 study, 16 deaths were recorded. However, while the applicant noted only 2 of these 16 deaths were related to adverse events, we stated that we remained concerned that further analysis may be needed to evaluate the safety of TECARTUS® and the longer term effects of the CRS and neurological events associated with the TECARTUS® therapy.

We invited public comments on whether TECARTUS® meets the substantial clinical improvement criterion.

Comment: A commenter submitted a comment stating that with regard to whether there is a high unmet need for Medicare patients with R/R MCL, two observations are important: (1) Median age at diagnosis of MCL is approximately 68 years old and (2) MCL is considered an incurable malignancy. The commenter stated that the median duration of remission is 3 to 5 years suggesting that the age at first relapse is approximately 70 years; this was reflected by the pivotal trial, Zuma 2, where over half of the patients were over age 65. The commenter stated that the decision to treat older patients with comorbid conditions was not taken lightly. The commenter stated that, rather then focus on the specific clinical outcomes observed with TECARTUS® in CMS' review and in publication, that they desired to lend support as evidenced by their experience with the technology and respond directly to CMS' concerns. The commenter concluded that they were able to demonstrate safety and efficacy data that parallel the clinical trial experience in spite of treating older patients with comorbid conditions, many of which would have failed to meet trial eligibility.

A second commenter stated their agreement with the assertion included in the new technology add-on payment application that the registration study population for the ZUMA–2 trial and the overall U.S. mantle cell lymphoma population are both representative of the Medicare population. The commenter stated that TECARTUS® has the potential to impact this population with an efficacy profile that is even stronger than that of approved CAR T-cell therapies for DLBCL.

A third commenter stated that while MCL and DLBCL share similar clinical presentations, they believe the key distinction between MCL and large B cell Lymphoma (LBCL) in relation to CAR T-cell therapy is that MCL has a leukemic phase in all MCL patients that both needs to be accounted for in production and accounts for a higher disease burden driving TECARTUS® CAR19 expansion. The commenter added that the real-world use of TECARTUS® is heavily skewed to an elderly patient population with most being age 65 or older and having new technology add-on payment support is critical to continued TECARTUS® usage.

Finally, a commenter stated support for CMS' desire for additional data and comment to illustrate that TECARTUS® meets the substantial clinical improvement criterion to support new technology add-on payment status.

Response: We appreciate the input from the commenters with regard to TECARTUS® and we have taken these comments into consideration in determining whether to approve TECARTUS® for the new technology add-on payment, as discussed below in this section.

Comment: In response to CMS' concern about the small sample size of the ZUMA–2 study, the applicant stated that sample size and power calculations for ZUMA–2 were carefully designed to demonstrate that TECARTUS® is an effective treatment for patients with r/r MCL who have not responded to currently available therapy. The

[567] Wang M, et al. KTE–X19 CAR T-Cell therapy in relapsed or refractory mantle-cell lymphoma. N Engl J Med. (2020) 382(14): 1331–1342.

[568] Pocock SJ. When (not) to stop a clinical trial for benefit. JAMA 2005;294:2228e30.

[569] Pocock SJ, Hughes MD. Practical problems in interim analyses, with particular regard to estimation. Control Clin Trials 1989;10(4 Suppl): 209Se21S.

[570] Montori VM, Devereaux PJ, Adhikari NK, Burns KE, Eggert CH, Briel M, et al. Randomized trials stopped early for benefit: A systematic review. JAMA 2005;294:2203e9.

[571] Bassler D, Briel M, Montori VM, Lane M, Glasziou P, Zhou Q, et al. Stopping randomized trials early for benefit and estimation of treatment effects: systematic review and meta-regression analysis. JAMA 2010;303:1180e7.

[572] Campo E, Rule S. Mantle cell lymphoma: evolving management strategies. *Blood.* 2015;125(1):48–55.

[573] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[574] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. Ann Oncol. 2015;26(6):1175–9.

applicant reiterated that the ORR achieved in ZUMA–2 was 93% which was significantly higher than the prespecified historical control and the pooled meta-analysis ORR. The applicant asserted the ZUMA–2 study design called for the primary analysis to be conducted after 60 subjects in Cohort 1 were treated with TECARTUS® and had the opportunity to be assessed for response 6 months after the week 4 disease assessment. The applicant added that a sample size of 60 subjects in cohort 1 had at least 96% power to distinguish between an active therapy with a true response rate of 50% or higher from a therapy with an ORR of 25% or less [575] [576] with a 1-sided alpha level of 0.025. The applicant added that the ZUMA–2 study reported an ORR of 93% (95% CI: 83.8%, 98.2%) after a single-dose of TECARTUS®, significantly higher than the prespecified historical control rate of 25% (p <0.0001) and the meta-analysis pooled ORR rate of 28% (95% CI: 23%, 34%) to salvage therapies that are currently available.[577] Lastly, in regard to this concern, the applicant stated the ZUMA–2 population, in which 57% of the study subjects were 65 years of age or older, was representative of the Medicare population.

In response to CMS' concerns about the potential for selection bias and the differences of the ORR among the first 60 patients as compared to that from all 74 patients, the applicant commented that the observed ORR in ZUMA–2 is consistently higher than the prespecified historical control rate or the pooled ORR reported in the meta-analysis whether comparing the 60 subjects of the primary analysis or the 74 subjects in the full analysis. The applicant stated that the ORR from the 6-study meta-analysis was 28% (95% CI: 23–34%) which when compared to the updated analysis for the efficacy analysis (n=60) ORR of 92% (95% CI: 81.6%, 97.2%) and the full analysis set (n=74) ORR of 84% (95% CI: 73.4%, 91.3%) continues to show no overlap of confidences intervals. Lastly, in response to this concern, the applicant states that it is important to note that ZUMA–2 was not stopped early and is ongoing with 18 months of follow-up data available.

In response to CMS' concern that the historical control may not be appropriate or representative of r/r MCL patients, and that ZUMA–2 was not designed to compare efficacy and safety of TECARTUS® to BTK inhibitors, the applicant commented that the prespecified historical control rate for ORR in ZUMA–2, the meta-analyses subsequently conducted, and a separate systematic literature review and sensitivity meta-analysis provide a complete review of published clinical studies (through February 2019). The applicant stated the prespecified historical control rate was based on two retrospective studies that were published at the time of ZUMA–2 protocol development; these two studies demonstrated that patients with r/r MCL who had ≥3 prior lines of therapy before receiving a BTK inhibitor had ORRs to salvage therapy of approximately 25%.[578] [579] The applicant asserted that subsequent to the initial historical control rate estimation, the applicant conducted a meta-analysis of 6 published clinical studies and commissioned an independent systematic literature review, resulting in an updated, sensitivity meta-analysis. The applicant added that the pooled ORR estimate from the 6-study meta-analysis [580] [581] [582] [583] [584] [585] (ORR: 28%, 95% CI, 23%, 34%) is reported in Table 3 in the TECARTUS® new technology add-on payment application. The applicant stated ZUMA–2 had no comparator arm because there was no effective standard therapy for patients with r/r MCL after they had progressed. Therefore, according to the applicant, an historical control was the only ethical and feasible study design for patients with r/r MCL who have not responded to the most promising therapies available, including BTK inhibitors. Lastly, the applicant asserts that the FDA recognizes a historical control as a valid comparison of the experimental group in clinical trials used to provide evidence that a product is safe and effective for its intended use.[586]

Lastly, in response to CMS' concern that a longer-term analysis of the population of interest is not available to evaluate the overall survival and mortality data, the applicant commented that updated efficacy and safety data was submitted in the TECARTUS® new technology add-on payment application dated December 31, 2019, which represented the first update following the primary analysis. The applicant then stated that an updated 18-month analysis, with a cut-off date of December 31, 2020, has been completed but is confidential. The applicant then stated that the data confirmed there were no changes to overall incidence in the following safety categories as compared to the primary analysis results: Adverse events, serious adverse events, related adverse events, related serious adverse events, any cytokine release syndrome (CRS), grade 3 or higher CRS, overall neurologic events, and grade 3 or higher neurologic events. The applicant added that there were no changes to comparisons of CRS or neurologic events across age group comparisons (≥65 years of age and <65 years of age). The applicant further stated two additional deaths occurred between the data cutoff dates for the primary analysis and that updated analysis due to disease progression: 18 of 68 Subjects in ZUMA–2 (26%) had died as of the December 31, 2019 updated analysis cutoff. The applicant added, of these, 4 deaths occurred >30 days through 3 months after infusion of TECARTUS® and 14 deaths occurred ≥3 months after infusion of TECARTUS®. The applicant further added that sixteen (16) of the 18 subjects died as a result of progressive disease; two subjects died due to AEs other than disease progression: 1 subject had a Grade 5 AE of Staphylococcal bacteremia (deemed

[575] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. Ann Oncol. 2015;26(6):1175–9.

[576] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[577] Wang M, et al. KTE–X19 CAR T-Cell therapy in relapsed or refractory mantle-cell lymphoma. N Engl J Med. (2020) 382(14): 1331–1342.

[578] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. Ann Oncol. 2015;26(6):1175–9.

[579] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[580] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. Ann Oncol. 2015;26(6):1175–9.

[581] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[582] Dreyling M, et al. Ibrutinib versus temsirolimus in patients with relapsed or refractory mantle-cell lymphoma: an international, randomised, open-label, phase 3 study. Lancet. 2016;387(10020):770–8.

[583] Epperla N, et al. Predictive factors and outcomes for ibrutinib therapy in relapsed/refractory mantle cell lymphoma—a ''real world'' study. Hematological Oncology. 2017:1–8.

[584] Wang M, et al. Observational study of lenalidomide in patients with mantle cell lymphoma who relapsed/progressed after or were refractory/intolerant to ibrutinib (MCL–004). J Hematol Oncol. 2017;10:171.

[585] Jain P, et al. Long-term outcomes and mutation profiling of patients with mantle cell lymphoma (MCL) who discontinued ibrutinib. Br J Haematol. 2018a;183:578–87.

[586] Rare Diseases and Orphan Products—Institute of Medicine (US) Committee on Accelerating Rare Diseases Research and Orphan Product Development; Field MJ, Boat TF, editors. Rare Diseases and Orphan Products: Accelerating Research and Development. Washington (DC): National Academies Press (US); 2010. 3, Regulatory Framework for Drugs for Rare Diseases. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK56185/*.

related to conditioning chemotherapy and TECARTUS®), and 1 subject had a Grade 5 AE of organizing pneumonia (deemed related to conditioning chemotherapy).

Response: We thank the applicant for its comment and additional information regarding the substantial clinical improvement criterion. After consideration of the comments received, we agree with the applicant and commenters that TECARTUS® represents a substantial clinical improvement over existing therapies for relapsed and refractory MCL because TECARTUS® allows access to a treatment option for patients unresponsive to or ineligible for currently available therapies, including patients who have progressed following a prior BTK inhibitor. In addition, we believe that the ORR of 93% seen after one dose with TECARTUS®, and the difference in ORR between use of TECARTUS® and the historical controls demonstrate a substantial clinical improvement over existing technologies.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined, for the reasons stated previously, that TECARTUS® meets the criteria for approval of the new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2022. Cases involving the use of TECARTUS® that are eligible for new technology add-on payments will be identified by procedure codes XW033M7 (Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) or XW043M7 (Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7).

In its application, the applicant estimated that the cost of TECARTUS® is $373,000.00 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. However, in their public comment the applicant stated that effective April 15, 2021, the WAC for TECARTUS® is $399,000.00 per each patient-specific, single-infusion bag.[587] As a result, the maximum new technology add-on payment for a case involving the use of TECARTUS® is $259,350 for FY 2022.

o. VEKLURY® (remdesivir)

Gilead Sciences, Inc. submitted an application for new technology add-on payments for VEKLURY® (remdesivir) for FY 2022. VEKLURY® is a nucleotide analog that inhibits viral RNA-dependent RNA polymerases, demonstrating activity countering viral pathogens such as severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2), the virus that causes coronavirus disease 2019 (COVID–19).

According to the applicant, spread of COVID–19 is presumed largely to occur through respiratory droplets and approximately 80% is predicted to occur by pre- and asymptomatic individuals. The applicant asserted viral incubation averages 3–7 days and can occur for up to 2 weeks.[588] According to the applicant, once infected, approximately 81% of COVID–19 patients experience mild disease, 14% experience severe disease, and 5% experience critical disease.[589] The applicant stated that severity of disease changes with age—approximately 113 in 100,000 people aged 18–49 years are hospitalized, compared to 250 in 100,000 aged 50–64 years and 451 in 100,000 aged 65+.[590] The applicant asserted that other risk factors for severity include underlying comorbidities but severe illness can occur in otherwise healthy individuals at any age.[591]

According to the applicant, patients who present to the hospital with evidence of pneumonia may require supplemental oxygen in severe cases, or, those with critical illness may develop hypoxemic respiratory failure, acute respiratory distress syndrome, and multiorgan failure that requires ventilation support.[592] The applicant cited one study of 2,482 hospitalized COVID–19 patients, in which 32% of patients were admitted to the intensive care unit (ICU) for a median stay of 6 days and 19% received invasive mechanical ventilation, 53% of whom died in the hospital.[593]

According to the applicant, VEKLURY® received FDA approval for use in the inpatient setting on October 22, 2020 via Priority Review and had received Fast Track designation.[594] Under the New Drug Application (NDA) FDA approval, VEKLURY® is indicated for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID–19 requiring hospitalization.[595] [596] Prior to its approval, on May 1, 2020, VEKLURY® received an Emergency Use Authorization (EUA) from FDA for the treatment of suspected or laboratory-confirmed COVID–19 in adults and children hospitalized with severe disease.[597] VEKLURY® continues to have an EUA for pediatric patients (12 years of age or younger weighing at least 3.5 kg or weighing 3.5 kg to less than 40 kgs) for emergency use to treat suspected or laboratory-confirmed COVID–19 in hospitalized pediatric patients.[598] [599]

According to the applicant, VEKLURY® has been available under the EUA since it was first issued in May 2020 for emergency use in the inpatient setting for patients with COVID–19. The applicant asserted that between July 1, 2020 and September 30, 2020, it entered

[587] FDB MedKnowledge Product Update Report: 4/15/2021.

[588] Cascella M, Rajnik M, Cuomo A, et al. Features, Evaluation, and Treatment of Coronavirus (COVID–19). StatPearls, published August 10, 2020. *https://www.ncbi.nlm.nih.gov/books/NBK554776/.*

[589] McIntosh K, Hirsch MS (ed), and Bloom A (ed). Coronavirus disease 2019 (COVID–19): Clinical features. UpToDate, updated September 14, 2020. *https://www.uptodate.com/contents/coronavirusdisease-2019-covid-19-clinical-features.*

[590] Centers for Disease Control and Prevention (CDC). COVIDView A weekly Surveillance Summary of U.S. COVID–19 Activity, published September 11, 2020. *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.*

[591] McIntosh K, Hirsch MS (ed), and Bloom A (ed). Coronavirus disease 2019 (COVID–19): Clinical features. UpToDate, updated September 14, 2020. *https://www.uptodate.com/contents/coronavirusdisease-2019-covid-19-clinical-features.*

[592] Ibid.

[593] Kim L, Garg S, O'Halloran A, et al. Risk Factors for Intensive Care Unit Admission and Inhospital Mortality Among Hospitalized Adults Identified through the US Coronavirus Disease 2019 (COVID–19)-Associated Hospitalization Surveillance Network (COVID–NET). Clinical Infectious Diseases. 2020; ciaa1012, *https://doi.org/10.1093/cid/ciaa1012.*

[594] FDA. FDA News Release: FDA Approves First Treatment for COVID–19, published October 22, 2020. *https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19.*

[595] VEKLURY® NDA approval: *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf; https://www.fda.gov/media/143189/download.*

[596] FDA. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of VEKLURY® (remdesivir): *https://www.fda.gov/media/137566/download.*

[597] FDA News Release: Coronavirus (COVID–19) Update: FDA Issues Emergency Use Authorization for Potential COVID–19 Treatment. Published May 1, 2020. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment.*

[598] VEKLURY® EUA: *https://www.fda.gov/media/137564/download.*

[599] FDA News Release: COVID–19 Update: FDA Broadens Emergency Use Authorization for VEKLURY® (remdesivir) to Include All Hospitalized Patients for Treatment of COVID–19, published August 28, 2020. *https://www.fda.gov/news-events/press-announcements/covid-19-update-fda-broadens-emergency-use-authorization-VEKLURY®-remdesivir-include-all-hospitalized.*

into an agreement with the U.S. Government to allocate and distribute commercially-available VEKLURY® across the country.[600] The applicant stated that under this agreement, the first sale of VEKLURY® was completed on July 10, 2020. The applicant stated that they transitioned to a more traditional, unallocated model of distribution as of October 1, 2020.

According to the applicant, as of August 1, 2020, VEKLURY® is uniquely identified by ICD–10–PCS codes XW033E5 (Introduction of remdesivir anti-infective into peripheral vein, percutaneous approach, new technology group 5) and XW043E5 (Introduction of remdesivir anti-infective into central vein, percutaneous approach, new technology group 5). Prior to August 1, 2020, the generic, non-COVID–19 ICD–10–PCS codes 3E033GC (Introduction of other therapeutic substance into peripheral vein, percutaneous approach) and 3E043GC (Introduction of other therapeutic substance into central vein, percutaneous approach) could be reported for the use of VEKLURY®.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted VEKLURY® is a SARS–CoV–2 nucleotide analog RNA polymerase inhibitor, and that there are no other antiretroviral therapies that have received an EUA or an approval from FDA to treat COVID–19. The applicant stated, however, that convalescent plasma has also received an EUA for the treatment of hospitalized patients with COVID–19.[601] [602] According to the applicant, convalescent plasma is collected from individuals who have been infected with SARS–CoV–2 and have developed antibodies to the virus. The applicant stated that plasma is transfused into infected patients with the expectation that the antibodies present will neutralize the virus.[603] The applicant asserted this mechanism of action is different from VEKLURY® which works as a nucleotide analog to inhibit viral replication. We noted that, as a result of their evaluation of the most recent information available, on February 4, 2021 FDA reissued the EUA for convalescent plasma. The EUA authorizes only the use of high titer COVID–19 convalescent plasma, for the treatment of hospitalized patients early in the course of disease. The use of low titer COVID–19 convalescent plasma is not authorized under the EUA.[604]

We noted that another inpatient treatment for COVID–19, Olumiant® (baricitinib), in combination with VEKLURY®, has received an EUA. Specifically, the EUA for Olumiant®, which should be administered in combination with VEKLURY®, is for the treatment of COVID–19 in certain hospitalized patients requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).[605] Olumiant® is a Janus kinase (JAK) inhibitor with prior FDA approval for another indication—the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.[606]

According to the applicant, because of the rapidly evolving nature of the COVID–19 pandemic, there is not a current standard of care used across hospitals in the United States.

With regard to the second criterion, whether the technology is assigned to the same or a different MS–DRG, the applicant asserted that as there no other antiretroviral therapies for the treatment of patients with COVID–19, VEKLURY® could not be assigned to the same MS–DRG as existing technologies.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted VEKLURY® represents a novel treatment option for patients with COVID–19 who are hospitalized. The applicant stated COVID–19 is a completely separate disease from those caused by other coronaviruses. The applicant asserted severe acute respiratory syndrome (SARS) is caused by the coronavirus SARS–CoV and was first reported in 2003. The applicant stated SARS symptoms were similar to COVID–19 and included high fever, body aches, and mild respiratory symptoms but no treatments specific to SARS–CoV have been developed.[607] According to the applicant, MERS–CoV, the Middle east respiratory syndrome coronavirus, was first identified in 2012 and has some similarities in etiology to SARS–CoV–2 but lacks treatment options.[608]

Based on the applicant's statements as summarized previously, the applicant believes that VEKLURY® is not substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion. In the proposed rule, we noted that although there may not be other antiretrovirals available for the treatment of COVID–19, cases involving VEKLURY® may map to the same MS–DRGs as other treatments for COVID–19. We also noted that VEKLURY® may not treat a different disease or patient population as existing treatments for COVID–19, as Olumiant® (administered with VEKLURY®) and convalescent plasma appear to treat the same disease and similar patient population.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we revised our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. We stated that new technologies that have not received FDA approval do not meet the newness criterion. In addition, we stated we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective. For these reasons, we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial

[600] Veklury (remdesivir)—ASPR's Portfolio of COVID–19 Medical Countermeasures Made Available as a Licensed Product *https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/Veklury.aspx.*

[601] Convalescent plasma EUA: *https://www.fda.gov/media/141477/download.*

[602] FDA. Emergency Use Authorizations: Drug and Biological Products. 2020. *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.*

[603] Liu STH, Li MH, Baine I, at al. Convalescent plasma treatment of severe COVID–19: A propensity score-matched control study. *Nature Medicine.* 2020. *https://doi.org/10.1038/s41591-020-1088-9.*

[604] FDA reissued the EUA on March 9, 2021. FDA In Brief: FDA Updates Emergency Use Authorization for COVID–19 Convalescent Plasma to Reflect New Data, published February 4, 2021. *https://www.fda.gov/news-events/fda-brief/fda-brief-fda-updates-emergency-use-authorization-covid-19-convalescent-plasma-reflect-new-data* and *https://www.fda.gov/media/141477/download.*

[605] Olumiant® EUA: *https://www.fda.gov/media/143822/download.*

[606] Olumiant® (baricitinib) [package insert]. FDA, revised July 8, 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/207924s002lbl.pdf.*

[607] CDC. Severe Acute Respiratory Syndrome (SARS), updated December 6, 2017. *https://www.cdc.gov/sars/index.html.*

[608] CDC. About MERS, Updated August 2, 2019. *https://www.cdc.gov/coronavirus/mers/about/index.html.*

clinical improvement over existing medical services or technologies. We also finalized at 42 CFR 412.87(c) (subsequently redesignated as 412.87(e)) that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances, licensures, and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to § 412.87(e)(2) to indicate that new technologies must receive FDA marketing authorization (for example, pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; approval of a New Drug Application (NDA); or Biologics License Application (BLA) licensure) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As noted in the FY 2021 IPPS/LTCH PPS final rule, this technical clarification did not change our longstanding policy for evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, and we continue to consider FDA marketing authorization as representing that a product has received FDA approval or clearance for purposes of eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

An EUA by the FDA allows a product to be used for emergency use, but under our longstanding policy, we believe it would not be considered an FDA marketing authorization for the purpose of new technology add-on payments, as a product that is available only through an EUA is not considered to have FDA approval or clearance. Therefore, under the current regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible for new technology add-on payments. Therefore, cases involving hospitalized pediatric patients (12 years of age or younger weighing at least 3.5 kg or weighing 3.5 kg to less than 40 kgs) receiving VEKLURY® for emergency use to treat suspected or laboratory-confirmed COVID–19 are not eligible for new technology add-on payment.

We refer the reader to our comment solicitation in section II.F.7 of the preamble of the proposed rule (86 FR 25394 through 25395) regarding how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA.

We also invited public comments on any implications of the distribution agreement described previously with regard to the market availability of VEKLURY®.

We also refer the reader to our proposal in section II.F.8 of the preamble of the proposed rule (86 FR 25394) to extend the new COVID–19 treatments add-on payment (NCTAP) through the end of the fiscal year in which the PHE ends for certain products and discontinue NCTAP for products approved for new technology add-on payments in FY 2022. We also refer the reader to section II.F.8 of the preamble of this final rule, where we discuss our finalized policy to extend the NCTAP through the end of the fiscal year in which the PHE ends for all eligible products.

We invited public comments on whether VEKLURY® meets the newness criterion.

Comment: The applicant submitted a comment in response to our concerns regarding newness. With respect to our concern that cases involving VEKLURY® may map to the same MS–DRGs as other treatments for COVID–19 and that VEKLURY® may not treat a different disease or patient population as existing treatments for COVID–19, as Olumiant® (administered with VEKLURY®) and convalescent plasma appear to treat the same disease and similar patient population, the applicant agreed that cases involving VEKLURY® may map to the same MS–DRG as other treatments for COVID–19 because those cases are likely to have the same principal diagnosis.

With regard to our concern that VEKLURY may not treat a different disease or patient population, the applicant stated that COVID–19 is noted to have discrete phases, including an early infectious phase, a pulmonary phase, and a hyperinflammatory phase. According to the applicant, VEKLURY® has a unique mechanism of action and may be used in patients at different phases of COVID–19, which differentiates it from other COVID–19 therapies.[609] The applicant also stated that the utility of antiviral agents such as VEKLURY® is expected to be strongest in the earliest phases of COVID–19, while that of immunomodulators such as Olumiant or dexamethasone is likely strongest in the later phases of the COVID–19. The applicant also stated that COVID–19 drugs are currently used in conjunction with one another for effective treatment, depending on the patient population. For example, the NIH recommends VEKLURY® with or without dexamethasone for patients hospitalized on low-flow oxygen.[610] Similarly, for patients hospitalized with high-flow oxygen/non-invasive ventilation the NIH guidelines recommend use of VEKLURY® with dexamethasone, and tocilizumab as an addition in case of rapidly progressive disease with systemic inflammation. The applicant noted that Olumiant is only recommended for use with VEKLURY® as an alternative to dexamethasone + VEKLURY® when corticosteroids cannot be used. Further, the applicant stated that the Olumiant EUA is for use in combination with VEKLURY®, and Olumiant is not yet FDA approved for the treatment of COVID–19. Current NIH treatment guidelines recommend against use of low-titer convalescent plasma for treatment of COVID–19, and recommends against use of convalescent plasma for hospitalized patients who do not have impaired immunity.[611]

Response: We thank the applicant for its comment and additional input regarding the newness criterion. After consideration of the comment received and information submitted by the applicant, we continue to believe that the new use of the technology may involve the treatment of the same or similar type of disease and the same or similar patient population as existing technologies that treat COVID–19, such as Olumiant (administered with VEKLURY®). However, we agree that VEKLURY® does not use the same or a similar mechanism of action to achieve a therapeutic outcome when compared to existing treatment. VEKLURY® works as a nucleotide analog to inhibit viral replication and there are no other antiretroviral therapies that have received an EUA or an approval from

[609] Siddiqi HK, Mehra MR. COVID–19 illness in native and immunosuppressed states: A clinical therapeutic staging proposal. J. Heart Lung Transplant. 2020; 39: 405–407. *https://doi.org/10.1016/j.healun.2020.03.012.*

[610] National Institutes of Health. Therapeutic Management of Adults with COVID–19. Last updated May 24, 2021. *https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/.*

[611] Ibid.

FDA to treat COVID–19. Therefore, we believe that VEKLURY® is not substantially similar to an existing technology and meets the newness criterion with an indication for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID–19 requiring hospitalization. Consistent with our longstanding policy, we consider the newness period to begin on October 22, 2020, when the NDA for VEKLURY® was approved by the FDA. We refer the reader to section II.F.7. of this final rule for a discussion of the comment solicitation regarding the newness period for products available through an EUA for COVID–19 including a summary of the comments received from the applicant and other commenters regarding this solicitation.

With regard to the cost criterion, the applicant used the FY 2019 MedPAR LDS and the February through June 2020 Electronic Data Interchange (EDI) transaction data to identify applicable cases. The applicant used the FY 2022 thresholds and the FY 2019 NPRM IPPS/LTCH impact file to standardize charges. As COVID–19 is an emergent disease, the applicant asserted that FY 2019 MedPAR claims may not be reflective of actual cases. Accordingly, and as summarized below, the applicant identified the FY 2019 MedPAR cases as proxy COVID–19 cases in its cost analysis. To supplement and confirm its MedPAR findings, the applicant used EDI data that includes actual COVID–19 cases from February through June 2020 to capture what the applicant described as true COVID–19 MS–DRG mapping and charges.

For the MedPAR LDS cases, the applicant used B97.29 with a manifestation code (J12.89 or J20.8 or J40 or J22 or J98.8 or J80). According to the applicant, this is based on the CDC guidance which specifies use of B97.29 with additional coding to identify the manifestation prior to the April 1, 2020 COVID–19 code. The applicant developed 3 sensitivity scenarios to further differentiate the MedPAR cases; Scenario 1: All Proxy COVID–19, Scenario 2: Proxy COVID–19 without ventilation, and Scenario 3: Proxy COVID19 with ventilation. Next, the applicant analyzed linked 837 and 835 inpatient EDI transaction sets that were processed February through June of 2020. The 837 and 835 transaction sets are updated daily and stored in the Inovalon provider research datasets, accounting for approximately 5–7% of the total Medicare FFS volume nationally on average. For cases prior to April 1, the applicant used the same coding as the MedPAR analysis. For claims on or after April 1, 2020, the applicant used the actual COVID–19 code U07.1. The applicant then identified cases using the 3 sensitivity scenarios; Scenario 4: All COVID–19, Scenario 5: COVID–19 without ventilation, and Scenario 6: COVID–19 with ventilation.

The claim search conducted by the applicant identified 1,726 cases mapping to 25 MS–DRGs for scenario one, 274 cases mapping to eight MS–DRGs for scenario two, 1,393 cases mapping to 21 MS–DRGs for scenario three, 3,826 cases mapping to 21 MS–DRGs for scenario four, 859 cases mapping to seven MS–DRGs for scenario five, and 2,917 cases mapping to 14 MS–DRGs for scenario six. The MS–DRGs identified in each scenario are listed in the following tables.

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List of Identified MS-DRGs With Volumes Higher Than 10 Cases For Scenario 1: All Proxy COVID-19	
MS-DRG	**Description**
871	Septicemia or Severe Sepsis without Mv >96 Hours with MCC
193	Simple Pneumonia & Pleurisy with MCC
202	Bronchitis & Asthma with CC/MCC
189	Pulmonary Edema & Respiratory Failure
190	Chronic Obstructive Pulmonary Disease with MCC
291	Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxyg
194	Simple Pneumonia & Pleurisy with CC
191	Chronic Obstructive Pulmonary Disease with CC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
870	Septicemia or Severe Sepsis with Mv >96 Hours or Peripheral Extracorporea
177	Respiratory Infections & Inflammations with MCC
872	Septicemia or Severe Sepsis without Mv >96 Hours without MCC
853	Infectious & Parasitic Diseases with O.R. Procedure with MCC
195	Simple Pneumonia & Pleurisy without CC/MCC
207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Periphe
166	Other Resp System O.R. Procedures with MCC
203	Bronchitis & Asthma without CC/MCC
205	Other Respiratory System Diagnoses with MCC
682	Renal Failure with MCC

308	Cardiac Arrhythmia & Conduction Disorders with MCC
192	Chronic Obstructive Pulmonary Disease without Cc/MCC
292	Heart Failure & Shock with CC
178	Respiratory Infections & Inflammations with CC
698	Other Kidney & Urinary Tract Diagnoses with MCC
280	Acute Myocardial Infarction, Discharged Alive with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 2: Proxy COVID-19 with Ventilation	
MS-DRG	**Description**
871	Septicemia or Severe Sepsis without Mv >96 Hours w MCC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
189	Pulmonary Edema & Respiratory Failure
870	Septicemia or Severe Sepsis with Mv >96 Hours or Peripheral Extracorporea
291	Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxyg
207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Periphe
193	Simple Pneumonia & Pleurisy with MCC
190	Chronic Obstructive Pulmonary Disease with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 3: Proxy COVID-19 without Ventilation	
MS-DRG	**Description**
871	Septicemia or Severe Sepsis without Mv >96 Hours w MCC
193	Simple Pneumonia & Pleurisy w MCC
202	Bronchitis & Asthma with CC/MCC
190	Chronic Obstructive Pulmonary Disease with MCC
194	Simple Pneumonia & Pleurisy with CC
189	Pulmonary Edema & Respiratory Failure
291	Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxyg
191	Chronic Obstructive Pulmonary Disease with CC
872	Septicemia or Severe Sepsis without Mv >96 Hours without MCC
177	Respiratory Infections & Inflammations with MCC
195	Simple Pneumonia & Pleurisy without CC/MCC
203	Bronchitis & Asthma without CC/MCC
853	Infectious & Parasitic Diseases with O.R. Procedure with MCC
205	Other Respiratory System Diagnoses with MCC
178	Respiratory Infections & Inflammations with CC
292	Heart Failure & Shock with CC
192	Chronic Obstructive Pulmonary Disease without CC/MCC
280	Acute Myocardial Infarction, Discharged Alive with MCC
166	Other Resp System O.R. Procedures with MCC
682	Renal Failure with MCC
308	Cardiac Arrhythmia & Conduction Disorders with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 4: All COVID-19	
MS-DRG	**Description**
177	Respiratory Infections & Inflammations with MCC
871	Septicemia or Severe Sepsis without Mv >96 Hours with MCC
870	Septicemia or Severe Sepsis with Mv >96 Hours or Peripheral Extracorporea
207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Periphe
178	Respiratory Infections & Inflammations with CC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
193	Simple Pneumonia & Pleurisy with MCC
179	Respiratory Infections and Inflammations without CC/MCC
004	Tracheostomy with Mv >96 Hours Or Principal Diagnosis Except Face, Mouth and Neck without Major O.R.
194	Simple Pneumonia & Pleurisy with CC
853	Infectious & Parasitic Diseases with O.R. Procedure with MCC
377	Gastrointestinal Hemorrhage with MCC
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC
682	Renal Failure with MCC
981	Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC
291	Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxyg
480	Hip and Femur Procedures Except Major Joint with MCC
637	Diabetes with MCC
689	Kidney and Urinary Tract Infections with MCC
195	Simple Pneumonia & Pleurisy without CC/MCC
698	Other Kidney & Urinary Tract Diagnoses with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 5: COVID-19 and Ventilation	
MS-DRG	**Description**
870	Septicemia or Severe Sepsis with Mv >96 Hours or Peripheral Ecmo
207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Peripheral Ecmo
871	Septicemia or Severe Sepsis without Mv >96 Hours with MCC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
177	Respiratory Infections & Inflammations with MCC
004	Tracheostomy with Mv >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R.
853	infectious & Parasitic Diseases with O.R. Procedure with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 6: COVID-19 without Ventilation	
MS-DRG	**Description**
177	Respiratory Infections & Inflammations with MCC
871	Septicemia or Severe Sepsis without Mv >96 Hours with MCC
178	Respiratory Infections & Inflammations with CC
193	Simple Pneumonia & Pleurisy with MCC
179	Respiratory Infections and Inflammations without CC/MCC
194	Simple Pneumonia & Pleurisy with CC
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC
682	Renal Failure with MCC
377	Gastrointestinal Hemorrhage with MCC
291	Heart Failure & Shock w MCC or Peripheral Ecmo
637	Diabetes with MCC
195	Simple Pneumonia & Pleurisy without CC/MCC
689	Kidney and Urinary Tract Infections with MCC
853	Infectious & Parasitic Diseases with O.R. Procedure with MCC

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The applicant determined an average unstandardized case weighted charge per case of $56,643 for Scenario 1; $82,733 for Scenario 2; $51,100 for Scenario 3; $75,891 for Scenario 4; $131,004 for Scenario 5; and $59,393 for Scenario 6.

The applicant stated that 33 percent of the length of stay charges from relevant cases were removed as charges for and related to the prior technologies in order to estimate the potential decrease in length of stay achieved by use of VEKLURY®. The applicant stated that these length of stay charges were removed from relevant cases to conservatively estimate the potential reduction in charges due to decreased length of stay through use of VEKLURY®. The applicant asserted that this offset was determined based on findings from the Adaptive COVID–19 Treatment Trial (ACTT–1), which found those treated with VEKLURY® had a median recovery time of 10 days, as compared with 15 days for those who received placebo.

After calculating the average standardized charge per case for all scenarios, the applicant calculated the standardized charge per case for each MS–DRG. Next, for the analysis involving MedPAR, the applicant indicated that it applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges of 13.1 percent. We note that the inflation factor used in the FY 2021 IPPS/LTCH PPS final rule was 13.2 percent (1.13218) (85 FR 59039), which would have increased the inflated charges. For the analysis involving the EDI, the applicant used an inflation factor of 1.06353 or 6.4%, which it indicated was the same inflation factor used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039). We note that the inflation factor used in the FY 2021 IPPS/LTCH PPS final rule was 6.4% (1.06404) (85 FR 59039), but this does not affect the cost analysis. To calculate the charges for the technology, the applicant used the

national average CCR for the Drugs cost center of 0.187 from the FY 2021 Final IPPS rule. Lastly, the applicant calculated the case-weighted threshold amount and the final inflated average case-weighted standardized charge per case for each scenario.

The applicant stated that for Scenario 1, the final inflated average case-weighted standardized charge per case of $69,741 exceeded the average case-weighted threshold amount of $56,643 by $13,098. For Scenario 2, the final inflated average case-weighted standardized charge per case of $107,860 exceeded the average case-weighted threshold amount of $82,733 by $25,127. For Scenario 3, the final inflated average case-weighted standardized charge per case of $60,749 exceeded the average case-weighted threshold amount of $51,100 by $9,649. For Scenario 4, the final inflated average case-weighted standardized charge per case of $110,553 exceeded the average case-weighted threshold amount of $75,891 by $34,662. For Scenario 5, the final inflated average case-weighted standardized charge per case of $203,406 exceeded the average case-weighted threshold amount of $131,004 by $72,402. For Scenario 6, the final inflated average case-weighted standardized charge per case of $63,915 exceeded the average case-weighted threshold amount of $59,393 by $4,522.

The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, VEKLURY® meets the cost criterion.

We invited public comment on whether VEKLURY® meets the cost criterion.

Response: We did not receive comments regarding whether VEKLURY® meets the cost criterion. Based on the information included in the applicant's new technology add-on payment application, we believe that the VEKLURY® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that VEKLURY® represents a substantial clinical improvement over existing technologies because it shortens time to recovery in patients hospitalized with severe COVID–19. The applicant also asserted that it represents a substantial clinical improvement because the technology results in improved clinical status and a trend toward reduced mortality, with the most significant reduction seen in a post-hoc analysis of patients with COVID–19 on low-flow oxygen treated with VEKLURY®. The applicant further asserted VEKLURY® results in better clinical status for patients hospitalized with moderate COVID–19.

As stated previously, the applicant asserted that VEKLURY® represents a substantial clinical improvement over existing technologies because it shortens time to recovery in patients hospitalized with severe COVID–19. To support this claim, the applicant referenced published, peer-reviewed results from the ACTT–1 study, a multi-center, multi-country adaptive, double-blinded, placebo-controlled, randomized clinical trial. Patients with confirmed COVID–19 and evidence of lung involvement were randomly assigned to receive either VEKLURY® (n=532; 200 mg loading dose on day 1, followed by 100 mg daily for up to 9 additional days) or placebo (n=516) for up to 10 days. Patients could receive other treatments if a participating hospital had a written policy or guideline for treating COVID–19. The study was conducted in 60 trial sites across the world with a majority of trial sites within the United States (45 trial sites plus 13 sub-sites within the United States). The other sites were in Denmark (8), the United Kingdom (5), Greece (4), Germany (3), Korea (2), Mexico (2), Spain (2), Japan (1), and Singapore (1). The primary outcome measure of the ACTT–1 study was time to recovery, defined as the first day, from the time of enrollment into the study, that patients exhibited improvement in conditions based on hospitalization activity limitation, oxygen requirement, and medical care requirement.[612]

According to the applicant, as part of the trial design, an interim analysis was planned to determine if the study should be stopped early for futility, efficacy, or safety, if there was clear and substantial evidence of a treatment difference between study drug and placebo. An independent data and safety monitoring board met to review interim data and determined VEKLURY® was better than a placebo for the primary endpoint, time to recovery.[613] The applicant stated those treated with VEKLURY® had a median recovery time of 10 days, as compared with 15 days for those who received placebo (rate ratio for recovery, 1.29; 95% confidence interval [CI], 1.12 to 1.49; P <0.001), and the number of serious adverse events was lower in the VEKLURY® treated group.[614]

As stated previously, the applicant asserted VEKLURY® represents a substantial clinical improvement over existing technologies because use of VEKLURY® results in improved clinical status and reduced mortality in patients with COVID–19 on low-flow oxygen. According to the applicant, the pivotal ACTT–1 study showed an overall trend toward reduction in mortality with the most significant reduction observed in a post-hoc analysis of patients on low-flow oxyen treated with VEKLURY®. The overall mortality effect was not statistically significant. The applicant stated those treated with VEKLURY® continued to receive oxygen for fewer days (median, 13 days vs. 21 days) and the incidence of new oxygen use was lower in the VEKLURY® group (incidence, 36%; 95% CI, 26% to 47%) compared with the placebo group (incidence, 44%; 95% CI, 33% to 57%). In the post-hoc analysis, those receiving low-flow supplemental oxygen (that is, not those receiving noninvasive ventilation or high-flow oxygen, nor those receiving invasive mechanical ventilation or ECMO) treated with VEKLURY® had the largest reduction in mortality compared to the same cohort receiving the placebo (hazard ratio, 0.30; 95% CI, 0.14 to 0.64).[615]

As stated previously, the applicant asserted VEKLURY® results in better clinical status for patients hospitalized with moderate COVID–19. To support this claim, the applicant referenced published, peer-reviewed results from an open label, placebo controlled, randomized clinical trial. Patients with moderately severe COVID–19 (pulmonary infiltrates on imaging but oxygen saturation >94 percent on room air) were randomly assigned to receive either VEKLURY® plus continued standard of care for 10 days (n=197), VEKLURY® plus continued standard of care for 5 days (n=199), or continued standard of care (n=200). Standard of care could include use of concomitant medications such as steroids, hydroxychloroquine/chloroquine, lopinavir-ritonavir, tocilizumab, and azithromycin. The median time to start VEKLURY® treatment was 8 days after start of symptoms. The median length of treatment in the 10-day group was actually 6 days. Patients who improved could be discharged from the hospital before completing their assigned course of treatment. The study was conducted

[612] Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid–19—Final Report. *N Engl J Med. 2020*.

[613] The National Institutes of Health (NIH). NIH clinical trial shows Remdesivir accelerates recovery from advanced COVID–19, published April 29, 2020. *https://www.nih.gov/news-events/news-releases/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19*.

[614] Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid–19—Final Report. *N Engl J Med*. 2020.

[615] Ibid.

in 105 trial sites in the United States, Europe and Asia. The primary end point was assessment of clinical status on day 11 after initiation of treatment. Clinical status was assessed on a 7-point ordinal scale ranging from death (category 1) to discharged (category 7).[616]

According to the applicant, on day 11, patients with moderate COVID–19 treated with VEKLURY® for 5 days had a better clinical status compared with the standard of care (odds ratio 1.65; 95% CI, 1.09 to 2.48, P=0.02). The applicant stated the difference was not statistically significant between those treated with VEKLURY® for 10 days compared with the standard of care (P=0.18 by Wilcoxon rank sum test; the proportional odds assumption was not met for this comparison). The applicant asserted that post hoc analyses demonstrated improved clinical status in both the 5- and 10-day treated cohorts at 14 days (P=.03 for both groups). The applicant stated there were no significant differences in adverse events for those treated with Veklury for 5 days.[617]

In the proposed rule, we noted that the articles submitted by the applicant in support of substantial clinical improvement used study designs that may be subject to bias, such as the adaptive and open label design. The ACTT–1 study included a prespecified interim analysis as part of its adaptive design but no changes were made to the placebo arm. We were unclear whether this may suggest that VEKLURY® did not demonstrate superiority over the control. We also noted the ACTT–1 study showed considerable differences between geographic regions in median time to recovery for patients assigned to VEKLURY® compared to those assigned to placebo. For example, for the patient population studied at U.S. sites, the median time to recovery in the VEKLURY® group (n=310) vs. the placebo group (n=271) was 11 days vs. 16 days, respectively, whereas at non-US sites, patients treated with VEKLURY® (n=89) vs. placebo (n=81) experienced a median time to recovery of 8 vs. 12 days, respectively.[618] Furthermore, the ACTT–1 study allowed other simultaneous treatments based on individual hospital policies or guidelines, which we stated may have potentially confounded the results of the trial.

We invited public comments on whether VEKLURY® meets the substantial clinical improvement criterion.

Comment: We received comments in support of approval of the new technology add-on payment for VEKLURY® with the commenters stating that this technology is used as standard of care for the treatment of hospitalized patients with COVID–19.

Response: We appreciate these comments and will have considered them in our determination of substantial clinical improvement, which is discussed later in this section.

Comment: The applicant submitted comments in response to CMS' concerns regarding the substantial clinical improvement criterion. In response to the concern that the articles submitted used study designs that may be subject to bias, such as the adaptive and open label design, the applicant stated that the ACTT–1 study was the first stage of the ACTT program and in this first stage, the only treatment evaluated was VEKLURY® versus placebo. The applicant stated that this comparison was done in a randomized, double-blinded manner and that this addressed potential biases and mitigated potential confounding. The applicant also stated that the term ''adaptive'' applies to the entire ACTT program as a whole, rather than any individual stage and that based on the superiority of VEKLURY® over placebo demonstrated in ACTT–1, subsequent stages of the study (ACTT–2, ACTT–3, ACTT–4) evaluated the efficacy of the addition of other treatments (for example, baricitinib, interferon-β, dexamethasone) to VEKLURY®.

The applicant also responded to CMS' concern that the ACTT–1 study included a prespecified interim analysis as part of its adaptive design, but no changes were made to the placebo arm making it unclear whether VEKLURY® demonstrated superiority over the control. The applicant noted the final report on ACTT–1,[619] which stated that due to the rapid enrollment of the study, the planned interim analysis was conducted after enrollment of the study was completed and while follow-up of enrolled patients was ongoing. The applicant stated that at the recommendation of the independent Data and Safety Monitoring Board, the interim results were shared with the study team and then made public. The applicant stated that no changes were made in the randomization scheme; however, treating physicians could request to be made aware of the treatment assignment of patients who had not completed day 29 if clinically indicated (for example, because of worsening clinical status), and patients originally in the placebo group could be given VEKLURY®. Lastly, the applicant stated that analyses of the impact of this crossover were evaluated in sensitivity analyses and found to produce results similar to those of the prespecified primary analysis, which demonstrated superiority of VEKLURY® over placebo.

In response to CMS' concern that the ACTT–1 study showed considerable differences between geographic regions in median time to recovery for patients assigned to VEKLURY® compared to those assigned to placebo, the applicant stated that ACTT–1 was conducted early in the course of the COVID–19 pandemic and enrolled a diverse population of patients across the globe. The applicant also stated that at the time of the ACTT–1 study, the impact of COVID–19 was particularly great in Italy [620] and other parts of Europe, with hospital resources stretched to the point that healthcare resources were being reserved for those most likely to recover.[621] The applicant stated that at the time, there were no known effective treatments for COVID–19 and ventilators were in short supply and were being rationed or shared between multiple patients. The applicant noted that despite these regional differences, VEKLURY® remained superior to placebo across the entire study population, even within these subgroups. The applicant also noted that the study was designed a priori to evaluate the efficacy of VEKLURY® over placebo in the entire enrolled population, rather than individual subgroups, including those defined by region. Therefore, the applicant concluded, the geographic variation in time to recovery was likely due to differential impact of pandemic at the time, and different characteristics of patients in each region.

[616] Spinner CD, Gottlieb RL, Criner GJ, et al. Effect of Remdesivir vs Standard Care on Clinical Status at 11 Days in Patients With Moderate COVID–19 A Randomized Clinical Trial. *JAMA.* 2020; 342(11):1048–1057.

[617] Ibid. Spinner CD, Gottlieb RL, Criner GJ, et al. Effect of Remdesivir vs Standard Care on Clinical Status at 11 Days in Patients With Moderate COVID–19 A Randomized Clinical Trial. *JAMA.* 2020; 342(11):1048–1057.

[618] Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid–19—Final Report. *N Engl J Med.* 2020. See Supplementary Table S6.

[619] Beigel, JH, et al. Remdesivir for the Treatment of COVID–19—Final Report. New Engl J Med 2020; 282: 1813–26. DOI: 10.1056/NEJMoa2007764.

[620] Odone A, Delmonte D, Scognamiglio, T, Signorelli C. COVID–19 deaths in Lombardy, Italy: Data in context. Lancet Public Health. 2020; 6: E310. *https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(20)30099-/fulltext.*

[621] Doldi M, Moscatelli A, Ravelli A, Spiazzi R, Petralia P. Medicine and humanism in the time of COVID–19. Ethical choices. Acta Biomed [internet]. 2020 Nov. 10 [cited 2021 Jun. 3];91(4):e2020167. Available from: *https://mattioli1885journals.com/index.php/actabiomedica/article/view/10569.*

The applicant also referenced three additional studies presented at the World Microbe Forum in June 2021 that provided real-world data that demonstrated that effectiveness of VEKLURY® by baseline oxygen requirement subgroup and for mortality. The first study was an open label trial of 5 vs 10 days of treatment with VEKLURY® among patients hospitalized with severe COVID–19 compared to a real-world cohort of patients with severe COVID–19 who were not treated with VEKLURY® during the same time period, that is, through end of May 2020.[622] According to the applicant, in this analysis, among 1,974 patients treated with VEKLURY® for up to 10 days and 1,426 propensity score weighted control patients, VEKLURY® was associated with reduced mortality by day 28 both overall (Hazard Ratio [HR]: 0.46, 95% CI: 0.39–0.54) and in subgroups of baseline oxygen requirement (low flow, HR: 0.35, 95% CI: 0.26–0.46; high-flow/non-invasive ventilation, HR: 0.54, 95% CI: 0.42–0.69; invasive mechanical ventilation[IMV]/extracorporeal membrane oxygenation [ECMO], HR: 0.43, 95% CI: 0.39–0.54). In addition, after the 10-day treatment course of the trial extension, VEKLURY® was associated with an increased likelihood of hospital discharge by day 28 overall (HR: 1.64, 95% CI: 1.43–1.87) and in patients requiring low flow oxygen and high-flow/non-invasive ventilation at baseline (HR: 1.85, 95% CI: 1.56–2.20; and HR: 1.82, 95% CI: 1.40–2.37, respectively). No discharge benefit was observed in patients on IMV/ECMO at baseline.

The second study was a comparative analysis of real-world U.S. hospital chargemaster data from Premier Healthcare. In the study, 27,559 patients treated with VEKLURY® within 2 days of hospitalization and not requiring IMV/ECMO were propensity-score matched to 27,559 patients not treated with VEKLURY® in the same time period (August–November 2020).[623] According to the applicant, in patients not requiring oxygen, treatment with VEKLURY® was associated with a statistically significant reduction in mortality at both day 14 (HR: 0.69, 95%CI: 0.57–0.83) and day 28 (HR: 0.80, 95% CI: 0.68–0.94). Similarly, in patients requiring low-flow oxygen, treatment with VEKLURY® was associated with a statistically significant reduction mortality at both day 14 (HR: 0.67, 95% CI:0.59–0.77) and day 28 (HR: 0.76, 95% CI:0.68–0.86). Among patients requiring high-flow oxygen/non-invasive ventilation (NIV), treatment with VEKLURY® was associated with a statistically significant reduction in mortality at day 14 (HR: 0.81, 95% CI: 0.70—0.93); however, there was no statistically significant difference between the VEKLURY® and control groups at day 28.

The third study was a comparative analysis of integrated US hospital chargemaster and medical/pharmacy claims from HealthVerity that examined patients newly diagnosed with COVID–19 between May 1, 2020 (the date of Emergency Use Authorization from FDA) and May 3, 2021.[624] In this analysis, 24,856 patients treated with VEKLURY® were matched to 24,856 referent patients using risk set sampling and propensity score matching. In this data analysis, VEKLURY® was associated with reduced all-cause mortality by day 28 overall (HR: 0.77, 95% CI: 0.73–0.81) and in each subgroup of baseline oxygen requirement: Room air (HR: 0.87, 95% CI: 0.80–0.94), low flow oxygen (HR: 0.78, 95% CI: 0.69–0.87), high-flow oxygen/NIV (HR: 0.73, 95% CI: 0.66–0.80), and IMV/ECMO (HR: 0.76, 95% CI: 0.66–0.88). In addition, after completion of the 5-day treatment course, VEKLURY® was associated with a statistically significantly increased likelihood of hospital discharge overall (HR: 1.19, 95% CI: 1.14, 1.25). This improvement in hospital discharge was statistically significant for patients on room air at baseline (HR: 1.24, 95% CI: 1.16–1.32) and on low-flow oxygen at baseline (HR: 1.10, 95% CI: 1.00–1.22), and suggestive for patients high-flow/NIV at baseline (HR: 1.14, 95% CI: 0.98–1.33); no association was observed for hospital discharge among patients on ECMO/IMV.

In response to CMS' concerns that the ACTT–1 study allowed other simultaneous treatments based on individual hospital policies or guidelines, which may have potentially confounded the results of the trial, the applicant stated that although the study allowed simultaneous treatment with other drugs according to local guidelines or practices, the randomized, placebo-controlled, double-blinded design of the study guarded against bias and minimized potential confounding. The applicant also stated that despite the added noise of other simultaneous treatments, VEKLURY® was demonstrated to be effective at both the interim and final analyses. The applicant also noted that at the time of ACTT–1, no other treatments had demonstrated efficacy against COVID–19, and many, including hydroxychloroquine and lopinavir/ritonavir, were later found to be ineffective. According to the applicant, the RECOVERY trial first reported results demonstrating a benefit of glucocorticoids in June 2020, after ACTT–1 enrollment was complete.[625] Lastly, the applicant stated that the sensitivity analyses of ACTT–1 in which data were censored at earliest reported use of glucocorticoids or hydroxychloroquine still showed efficacy of VEKLURY®.[626]

Response: We thank the applicant for the additional data it provided and for its comment. We believe that the clarifications provided by the applicant addressed the concerns we noted in the FY 2022 IPPS/LTCH PPS proposed rule regarding the differences between geographic regions in median time to recovery between VEKLURY® patients and placebo patients. Although we note that controlling for the effect of geographic area would result in more robust analyses, we agree with the applicant that the geographic variation in time to recovery could be due to differential impact of pandemic at the time, and different characteristics of patients in each region. Lastly, we believe that the additional information from the applicant has addressed our concerns regarding the potential for bias in the study design and the prespecified interim analysis. Therefore, based on the data submitted by the applicant, we believe that VEKLURY® meets the substantial clinical improvement criterion because it because it has been shown to shorten time to recovery in patients hospitalized with severe COVID–19 by five days compared to patients treated with placebo and reduce mortality among patients receiving low-flow supplemental oxygen compared to the same cohort receiving the placebo.

After consideration of the public comments we received, we have determined that VEKLURY® meets all of the criteria for approval of new technology add-on payments, and we are approving new technology add-on payments for VEKLURY® for FY 2022 when used for adults and pediatric patients (12 years of age and older and

[622] Go et al, WMF, 2021

[623] Mozaffari et al, WMF, 2021.

[624] Chokkalingam et al, WMF, 2021.

[625] University of Oxford. Low-cost dexamethasone reduces death by up to one third in hospitalised patients with severe respiratory complications of COVID–19. 16 June 2020. *https://www.recoverytrial.net/news/low-costdexamethasone-reduces-death-by-up-to-one-third-in-hospitalised-patients-with-severe-respiratory-complications-ofcovid-19.*

[626] Beigel, JH, et al. Remdesivir for the Treatment of COVID–19—Final Report. New Engl J Med 2020; 282: 1813–26. DOI: 10.1056/NEJMoa2007764.

weighing at least 40 kg) for the treatment of COVID–19 requiring hospitalization. Cases involving VEKLURY® that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes XW033E5 (Introduction of remdesivir anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043E5 (Introduction of remdesivir anti-infective into central vein, percutaneous approach, new technology group 5).

In its application, the applicant stated that the cost per case for VEKLURY® is $3,120 per case. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the costs of the new medical service or technology, or 65 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, the maximum new technology add-on payment for a case involving the use of VEKLURY® is $2,028 for FY 2022. In addition, as discussed in section II.F.8, we established the NCTAP to pay hospitals the lesser of: (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID–19. As discussed in section II.F.8, we are finalizing to extend the NCTAP through the end of the fiscal year in which the PHE ends for all eligible products. We are also finalizing that we will reduce the NCTAP for an eligible case by the amount of any new technology add-on payments. Therefore, cases involving the use of VEKLURY® in FY 2022 are eligible for new technology add-on payments and NCTAP, with the NCTAP to be reduced by a maximum of $2,028 for the same treatment.

p. ZEPZELCA™ (lurbinectedin)

Jazz Pharmaceuticals submitted an application for new technology add-on payments for ZEPZELCA™ for FY 2022. According to the applicant, ZEPZELCA™ is an alkylating drug indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. ZEPZELCA™ is a marine-derived, synthetic antineoplastic compound that inhibits transcription-dependent replication stress and genome instability in tumor cells.

According to the applicant, small cell lung cancer (SCLC) is an aggressive type of lung cancer where patients that progress after first-line chemotherapy have a poor prognosis due to limited clinical benefit from currently available second-line chemotherapy. Patients relapsing or progressing more than 90 days after completion of first-line treatment are considered platinum sensitive and may be rechallenged with platinum-based chemotherapy.[627] The majority of SCLC treated patients show disease relapse and are eligible for second-line therapy; however, few second-line treatment options exist.[628]

According to the applicant, lung cancer overall is the second most common malignancy in the United States with 234,030 new cases and 154,050 deaths estimated in 2018.[629] Per the applicant, where most lung cancers are classified as non-SCLC, SCLC now comprises approximately 15% of all lung cancers. According to the applicant, SCLC is the most aggressive form of lung cancer characterized by rapid disease progression and early metastatic spread [630] [631] [632]—doubling in cell number about every 30 days and spreading quickly to lymph nodes and other organs.[633] The applicant stated that the Veterans Lung Cancer Study Group used a two-stage system for describing SCLC, with a limited-stage (30% of cases) which is confined to a smaller portion of the body, and an extensive-stage (70% of cases) where the tumor was widespread.[634] [635] Many patients with SCLC have substantial comorbidities that may affect performance status and treatment options.[636] A retrospective review analysis of Extensive-stage SCLC (ES–SCLC) patients found that when compared to patients at diagnosis, patients receiving second-line therapy were more likely to have congestive heart failure (67% vs 49%), thromboembolism (9% vs 2%), and depression (11% vs 7%).[637] Further, these patients receiving second-line therapy were more likely to have infectious disease (57% vs 43%), electrolyte disorders (50% vs 22%), anemia (45% vs 19%), neutropenia (17% vs <0.2%), thrombocytopenia (12% vs 2%), and diarrhea (7% vs 3%) compared to the incidence of these comorbidities at diagnosis of ES–SCLC.[638]

According to the applicant, the standard of care for first-line chemotherapy for both limited-stage SCLC and ES–SCLC is platinum doublet and, in the case of ES–SCLC, platinum doublet in combination with a checkpoint inhibitor. SCLC is sensitive to platinum-based chemotherapy in the first-line setting but almost universally relapses, requiring subsequent lines of therapy.[639] [640] [641] Once a patient relapses, the likelihood of response is highly dependent on time from initial therapy to relapse,[642] with survival based on the duration of remission.[643] According to the applicant, ES–SCLC is incurable; patients are treated with palliative intent, with a median survival of 7 to 11 months after diagnosis and with less than 5% survival at 2

[627] Garassino MC, et al. Outcomes of small-cell lung cancer patients treated with second-line chemotherapy: A multi-institutional retrospective analysis. *Lung Cancer* 72 (2011) 378–383.

[628] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: A single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045*.

[629] Tan WT, et al. Small Cell Lung Cancer (SCLC), Medscape, Oncology. Updated June 19, 2020. *Emedicine.medscape.com.*

[630] *Ibid.*

[631] Naito Y, et al. Rechallenge treatment with a platinum-based regimen in patients with sensitive relapsed small-cell lung cancer. *Medical Oncology* (2018) 35:61.

[632] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[633] Surveillance, Epidemiology, and End Results Program (SEER). Cancer stat facts: lung and bronchus cancer. *https://seer.cancer.gov/statfacts/html/lungb.html.* Accessed September 2020.

[634] *Ibid.*

[635] PDQ Adult Treatment Editorial Board. PDQ small cell lung cancer treatment. Bethesda, MD: National Cancer Institute. Updated March 20, 2020. *https://www.cancer.gov/types/lung/hp/small-cell-lung-treatment-pdq.* Accessed March 22, 2020. [PMID: 26389347].

[636] Kalemkerian GP. Small cell lung cancer. *Semin Respir Crit Care Med.* 2016;6(37):783–796.

[637] Danese M, et al. Comorbidity in patients with extensive disease small cell lung cancer. Presented at the AMCP Managed Care & Specialty Pharmacy Annual Meeting; March 27–30, 2017; Denver, CO.

[638] Ibid. Danese M, et al. Comorbidity in patients with extensive disease small cell lung cancer. Presented at the AMCP Managed Care & Specialty Pharmacy Annual Meeting; March 27–30, 2017; Denver, CO.

[639] Shao C, et al. Chemotherapy treatments, costs of care, and survival for patients diagnosed with small cell lung cancer: a SEER-Medicare study. *Cancer Med.* 2019;8:7613–7622.

[640] He J, et al. Survival, chemotherapy treatments, and health care utilization among patients with advanced small cell lung cancer: an observational study. *Adv Ther.* 2020;37:552–565.

[641] Karve SJ, et al. Comparison of demographics, treatment patterns, health care utilization, and costs among elderly patients with extensive-stage small cell and metastatic non-small cell lung cancers. *BMC Health Serv Res.* 2014;14:555.

[642] Shao C, et al. Chemotherapy treatments, costs of care, and survival for patients diagnosed with small cell lung cancer: a SEER-Medicare study. *Cancer Med.* 2019;8:7613–7622.

[643] Pietanza MC, et al. Small cell lung cancer: will recent progress lead to improved outcomes? *Clin Cancer Res.* 2015;21(10):2244–2255.

years.[644] [645] Even limited-stage disease is rarely cured with radical local therapy (surgery or radiotherapy), and systemic chemotherapy (platinum plus etoposide) remains the cornerstone of first-line treatment in SCLC.[646] Despite best management, the 5-year overall survival (OS) of even limited-stage SCLC is still only 15% to 25%.[647] [648]

The applicant asserted that while SCLC shows high sensitivity to first-line chemotherapy and radiotherapy, most patients develop disease relapse or progression within one year of treatment.[649] [650] [651] It is reported that about 80% of limited-disease SCLC patients and almost all patients with ES–SCLC will develop relapse or progression after first-line treatment. Without second-line chemotherapy, the median survival time is 2 to 4 months.[652] [653] The applicant stated that for patients classified as sensitive to first line treatment, due to remaining relapse-free for at least 3 months after treatment, rechallenge with the same chemotherapy regimen given as first line treatment is reasonable. For those classified as refractory (disease progression through first line treatment) and resistant (patients who show initial response to treatment but whose disease progresses within 3 months of completing chemotherapy), the second line treatment is Hycamtin (topotecan). According to the applicant, topotecan was the only preferred agent in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for second-line treatment of patients with a Chemotherapy-free Interval (CTFI) <6 months. In summarizing the evidence of topotecan efficacy, the applicant stated that studies showed a median survival of 6.8 to 7.8 months,[654] [655] [656] progression free survival of 2.7 to 3.5 months,[657] [658] [659] and a median time to progression of 13.3 weeks.[660] Furthermore, the applicant asserted that topotecan is associated with hematological toxicities such as anemia, neutropenia, thrombocytopenia, and febrile neutropenia.[661] [662] [663]

The applicant stated that since topotecan's approval in 1998, no other second-line SCLC treatment option had been approved until ZEPZELCA™ gained approval in June 2020. According to the applicant, ZEPZELCA™ is the first second-line treatment option for SCLC since 1998.

According to the applicant, the FDA approved ZEPZELCA™ on June 15, 2020 under the FDA's Accelerated Approval Program with Priority Review. ZEPZELCA™ was also granted Orphan Drug Designation by the FDA. ZEPZELCA™ is administered intravenously as a 3.2 mg/m^2 dose over one hour, repeated every 21 days until disease progression or unacceptable toxicity. ZEPZELCA™ will typically be administered in an outpatient clinic. However, per the applicant, because many patients with SCLC have substantial comorbidities that may necessitate hospitalization and initiation of treatment, the first infusion and possibly some additional infusions will be administered in the inpatient hospital setting.[664] The applicant submitted a request for a unique ICD–10–PCS code to identify the technology beginning FY 2022 and was granted approval for the following codes effective October 1, 2022: XW03387 (Introduction of lurbinectedin into peripheral vein, percutaneous approach, new technology group 7) and XW04387 (Introduction of lurbinectedin into central vein, percutaneous approach, new technology group 7).

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or a

[644] Simos D, et al. Third-line chemotherapy in small-cell lung cancer: an international analysis. *Clin Lung Cancer* (2014) 15 (2): 110–8.

[645] Pelayo AM, et al. Chemotherapy versus best supportive care for extensive small cell lung cancer. *Cochrane Database Syst Rev* (2013) 11: CD001990.

[646] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045*.

[647] Simos D, et al. Third-line chemotherapy in small-cell lung cancer: an international analysis. *Clin Lung Cancer* (2014) 15 (2): 110–8.

[648] Pelayo AM, et al. Chemotherapy versus best supportive care for extensive small cell lung cancer. *Cochrane Database Syst Rev* (2013) 11: CD001990.

[649] Naito Y, et al. Rechallenge treatment with a platinum-based regimen in patients with sensitive relapsed small-cell lung cancer. *Medical Oncology* (2018) 35:61.

15437.

[650] Shiozawa, T. Rechallenge with first-line platinum chemotherapy for sensitive-relapsed small-cell lung cancer. *Case Rep Oncol.* 2018;11:622–632.

[651] Horita N, et al. Topotecan for relapsed small-cell lung cancer: systematic review and meta-analysis of 1347 patients. *Sci Rep* 2015;5: 15437.

[652] Shiozawa, T. Rechallenge with first-line platinum chemotherapy for sensitive-relapsed small-cell lung cancer. *Case Rep Oncol.* 2018;11:622–632.

[653] Wakuda K et al. Efficacy of second-line chemotherapy in patients with sensitive relapsed small-cell lung cancer. *In vivo.* 33:2229–2234 (2019).

[654] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228. Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02). von Pawel JTopotecanTopote cancyclophosphamidecyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent. *J Clin*VolVol 17, No 2, 1999: 658–667.

[655] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[656] Von Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol.* Vol 17, No 2, 1999: 658–667.

[657] vonVon Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35. Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228. Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

[658] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

[659] von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35. Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228. Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

[660] vonVvon Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol.* Vol 17, No 2, 1999: 658–667.

[661] vonvVon Pawel JEvans TL, et al. CabazitaxelRandomized phase III trial of amrubicinCabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228. Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35. sensitive relapsed small-cell lung cancer: phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

[662] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

[663] Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

[664] Danese M, et al. Comorbidity in patients with extensive disease small cell lung cancer. Presented at the AMCP Managed Care & Specialty Pharmacy Annual Meeting; March 27–30, 2017; Denver, CO.

similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that the mechanism of action of ZEPZELCA™ is not the same or similar to the mechanism of action of currently available products used in the treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy. Per the applicant, ZEPZELCA™ is a novel synthetic antineoplastic marine derived compound with a unique mode of action and chemical structure, with a terminal half-life of 51 hours and total plasma clearance of 11 L/h (50%).[665] [666] According to the applicant, ZEPZELCA™ is a transcription inhibitor that binds DNA preferentially in quinine-rich sequences located within gene regulatory elements and induces a rapid degradation of transcribing RNA polymerase II that induces the eviction of oncogenic transcription factors and the silencing of their transcription program. The applicant states that ZEPZELCA™ has preclinical data which suggests that oncogenic transcription of DNA to RNA was selectively inhibited via the dual actions of RNA polymerase II degradation and the formation of DNA breaks, which leads to apoptosis.[667] The applicant further states that ZEPZELCA™ has been shown to induce immunogenic cell death,[668] and based on preclinical data, impacts the tumor microenvironment by altering the survival of tumor-associated macrophages (TAMs) and the production and function of key oncogenic inflammatory and growth factors.[669]

According to the applicant, topotecan is a semi-synthetic derivative of camptothecin with topoisomerase I-inhibitory activity that relieves torsional strain in DNA by inducing reversible single strand breaks. The pharmacokinetics of topotecan have been evaluated in cancer patients following doses of 0.5 to 1.5 mg/m^2 administered as a 30-minute infusion. Topotecan exhibits multiexponential pharmacokinetics with a terminal half-life of 2 to 3 hours. Total exposure area under the curve (AUC) is approximately dose proportional.[670] The applicant asserts that a clinical differentiator of ZEPZELCA™ from topotecan is the rate of hematologic adverse reactions including neutropenia, anemia, thrombocytopenia, and febrile neutropenia.[671] [672] [673]

Lastly, the applicant asserted that ZEPZELCA™ is not substantially similar to the more recently approved first-line treatments for ES–SCLC, TECENTRIQ® (atezolizumab) and IMFINZI® (durvalumab), both of which are PD–L1 blocking antibodies.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that ZEPZELCA™ will not map to MS–DRGs distinct from other treatments for SCLC.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that there have been no approved treatments for second-line treatment of SCLC since 1998 when topotecan was approved. Topotecan is indicated for the treatment of small cell lung cancers in patients with chemotherapy-sensitive disease after failure of first-line chemotherapy.[674] The applicant states that topotecan is approved for relapses at least 60 days after initiation of a platinum-containing first-line regimen. ZEPZELCA™ is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.[675] The applicant also stated that ZEPZELCA was listed as a preferred regimen by the NCCN Clinical Practice Guidelines for second-line treatment of patients with a chemotherapy free interval (CTFI) ≤6 months and recommended for patients with a CTFI >6 months.[676]

The applicant repeated results concerning the efficacy of topotecan and asserted that the efficacy results were achieved with a high rate of grade three and four hematologic Treatment Emergent Adverse Events (TEAEs).

In summary, the applicant asserted that ZEPZELCA™ meets the newness criterion because its mechanism of action is not the same or similar to the mechanism of action of currently available products used in the treatment of adult patients with metastatic SCLC and because it is indicated in patients with disease progression on or after platinum-based chemotherapy.

We invited public comments on whether ZEPZELCA™ is substantially similar to an existing technology and whether it meets the newness criterion.

Comment: The applicant submitted comments reiterating its belief that ZEPZELCA™ meets the newness criterion. First, the applicant stated that ZEPZELCA™'s mechanism of action is not the same or similar to that of existing technology approved for treatment of the same patient population. Per the applicant, SCLC is a difficult to treat, extraordinarily lethal malignancy [677] and that misregulated oncogenic transcriptions seem to direct SCLC initation and evolution, with transcription addiction being a feasible therapeutic target to treat the disease.[678] [679] Per the applicant, ZEPZELCA™ represents an innovative approach to conventional anti-cancer drugs, with an elegant mechanism of action that has been well characterized in peer-reviewed, scientific journals and is based on the inhibition of transcription-dependent replication stress and genome instability of tumor cells.[680] The applicant reiterated that

[665] ZEPZELCA website, ZEPZELCA™ prescribing information., Rev. 6/2020:. *https://www.zepzelcapro.com/.*

[666] Romano M. et al. Travectedin and lurbinectedin are effective against leukemic cells derived from patients affected by chronic and juvenile myelomonocytic leukemia. *European Journal of Cancer.* 50 (6 Suppl):48.

[667] Santamaria G, et al. Lurbinectedin reverses platinum dependent IRFI overexpression and nuclear localization, partially responsible for resistance to platinum drugs in ovarian cancer. *Proceedings of the American Association for Cancer Research* (2017) 58:311.

[668] Xie W, et al. Lurbinectedin synergizes with immune checkpoint blockade to generate anticancer immunity. *Oncoimmunology.* 2019;5;8(11):e1656502.

[669] Farago AF, et al. ATLANTIS: A phase III study of lurbinectedin/doxorubicin versus topotecan or cyclophosphamide/doxorubicin/vincristine in patients with small-cell lung cancer who have failed one prior platinum-containing line. *Future Oncol.* 2019;15(3):231–239.

[670] FDA website, Hycamtin (topotecan) prescribing information., Rev. 2/2014: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022453s002lbl.pdf.*

[671] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[672] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

[673] Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

[674] FDA website, Hycamtin (topotecan) prescribing information., Rev. 2/2014: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022453s002lbl.pdf* .

[675] ZEPZELCA website, ZEPZELCA™ prescribing information., Rev. 6/2020:. *https://www.zepzelcapro.com/.*

[676] NCCN Clinical Practice Guidelines in Oncology, Small Cell Lung Cancer. Version 4.2020, July 7, 2020. *https://nccn.org.*

[677] Gazdar AF, et al. Small-cell lung cancer: What we now, what we need to know and the path forward. Nat Rev Cancer (2017) 17 (12): 725–37.

[678] Rudin CM, et al. Molecular subtypes of small cell lung cancer: a synthesis of human and mouse model data. Nat Rev Cancer. (2019) 19 (5): 289–97

[679] Christensen CL, et al. Targeting transcriptional addictions in small cell lung cancer with a covalent CDK7 inhibitor. Cancer Cell. (2014) 26 (6): 909.22.

[680] Arrieta O, et al. New opportunities in a challenging disease: lurbinectedin for relapsed

ZEPZELCA™ is a novel synthetic antineoplastic compound, a marine-derived agent,[681] with a unique mode of action and chemical structure. The applicant stated that ZEPZELCA™ is not substantially similar to topotecan (brand name: Hycamtin), the only drug approved in over 20 years for patients with disease sensitive to treatment. The applicant further noted that topotecan is approved for relapses at least 60 days after initiation of a platinum containing first-line regimen.[682] The applicant also stated that ZEPZELCA is also not substantially similar to the more recently approved first-line treatments for ES–SCLC: TECENTRIQ® (atezolizumab) and IMFINZI® (durvalumab), both of which are PD–L1 blocking antibodies.

The applicant also stated that patient cases receiving intravenous infusion of ZEPZELCA™ will be discretely identified by unique ICD–10–PCS procedure codes for ZEPZELCA™ administration. The applicant stated that Jazz Pharmaceuticals' request for ZEPZELCA™-specific ICD–10–PCS codes was reviewed during the March 2021 ICD–10 Coordination and Maintenance (C&M) Committee meeting and that the effective date of these codes will be October 1, 2021.

Response: We thank the applicant for its comment. Based on our review of comments received and information submitted by the applicant as part of its FY 2022 new technology add-on payment application for ZEPZELCA™, as discussed in the proposed rule (86 FR 25353) and previously summarized, we agree with the applicant that ZEPZELCA™ has a unique mechanism of action as a transcription inhibitor in the treatment of metastatic SCLC.[683] Therefore, we believe ZEPZELCA™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence when ZEPZELCA™ was approved by FDA for the indication of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy, on June 15, 2020.

With respect to the cost criterion, the applicant conducted the following analysis to demonstrate that ZEPZELCA™ meets the cost criterion. For the primary cost analysis cohort the applicant used the selection criteria of the presence of a lung cancer code as defined by ICD–10–CM family C34 (Malignant neoplasm of bronchus and lung) as the principal diagnosis and the presence of any chemotherapy code as defined by ICD_10–CM Z51.11 (Encounter for antineoplastic chemotherapy), ICD–10–CM Z51.12 (Encounter for antineoplastic immunotherapy), or any ICD–10–PCS chemotherapy code. Additionally, the applicant performed three sensitivity analyses for the cost criterion. The first is a broad cohort with the selection criteria of the presence of at least one lung cancer code (C34xx) and the presence of any chemotherapy code as defined by ICD–10–CM code Z51.11 (Encounter for antineoplastic chemotherapy), Z51.12 (Encounter for antineoplastic immunotherapy), or any ICD–10–PCS chemotherapy code. The second and third analyses involved TECENTRIQ® and IMFINZI® which are both immunotherapy drugs that have FDA approval for use as part of the first-line treatment in patients with SCLC. These drugs are to be used along with chemotherapy. The second analysis is the ''TECENTRIQ®'' cohort with the selection criteria of the presence of at least one lung cancer code (C34xx) as either the principal or admitting diagnosis, and excluding cases with any ES–SCLC surgical codes. The final analysis, the ''IMFINZI®'' cohort, has the selection criteria of at least one of the following: (1) Presence of at least one lung cancer code (C34xx) and presence of any platinum-based chemotherapy code as defined by ICD–10–CM Z51.11 (Encounter for antineoplastic chemotherapy) or Z51.12 (Encounter for antineoplastic immunotherapy); (2) Presence of at least one lung cancer code (C34xx) and assigned to MS–DRGs for respiratory neoplasms (180–182). The applicant stated that ZEPZELCA™ is supplied in 4 mg single-dose vials with the recommended dose of 3.2 mg/m^2 by intravenous infusion over 60 minutes every 21 days until disease progression or unacceptable toxicity. Based on clinical study, the applicant stated that a single dose of ZEPZELCA™ ranged from 4.05 mg to 6.4 mg. To identify cases that may be eligible for the use of ZEPZELCA™, the applicant searched the FY 2019 MedPAR LDS file using these cohort selection criteria. The applicant stated that in all analyses, they imputed a case count of 11 for MS–DRGs with fewer than 11 cases and calculated the weighted average standardized charges across all MS–DRGs.

Based on the FY 2019 MedPAR LDS file, the applicant identified a total of 1,100 cases in the primary cohort (mapped to 17 MS–DRGs), 4,034 cases in the first sensitivity cohort (mapped to 195 MS–DRGs), 34,437 cases in the second sensitivity cohort (mapped to 253 MS–DRGs), and 24,209 cases in the third sensitivity cohort (mapped to 128 MS–DRGs). The applicant utilized the FY 2019 Final Rule with Correction Notice IPPS Impact File. Using the cases identified, the applicant then calculated the unstandardized average charges per case for each MS–DRG. The applicant expects that ES–SCLC patients will receive their initial dose of ZEPZELCA™ in the inpatient setting. The applicant then standardized the charges and inflated the charges by 1.13218 or 13.2 percent, the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule. The applicant removed charges associated with chemotherapy since treatment with ZEPZELCA™ would replace chemotherapy. To do so the applicant found the ratio of chemotherapy charges to radiology charges (0.14470075) from claims in the FY 2019 inpatient standard analytic file with a primary diagnosis of lung cancer (ICD–10–CM C34xx) and chemotherapy charges greater than zero. The applicant then added the charges for ZEPZELCA™ by converting the costs of a single treatment (two single-dose vials) to a charge by dividing the cost by the national average cost-to-charge ratio of 0.187 for pharmacy from the FY 2021 IPPS/LTCH PPS final rule. The applicant calculated a final inflated average case weighted standardized charge per case for the primary cohort as $206,030, and $182,895, $146,174, and $130,975 for sensitivity cohorts 1, 2 and 3, respectively. The applicant referred to the FY 2022 New Technology Thresholds data file to determine the average case-weighted threshold amount for the primary cohort as $79,420, and $70,499, $70,226, and $57,383 for sensitivity cohorts 1, 2 and 3, respectively. The final inflated average case-weighted standardized charge per case in the primary cohort and three

small-cell lung cancer. Comment in Lancet Oncology. *www.thelancet.com/oncology*, Published online March 27, 2020.*https://doi.org/10.1016/S1470–2045(20)30097–8*.

[681] Romano M. et al. Travectedin and lurbinectedin are effective against leukemic cells derived from patients affected by chronic and juvenile myelomonocytic leukemia. European Journal of Cancer. 50 (6 Suppl):48.

[682] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. Lancet Oncology. *www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470–2045*.

[683] Farago AF, et al. ATLANTIS: a phase III study of lurbinectedin/doxorubicin versus topotecan or cyclophosphamide/doxorubicin/vincristine in patients with small-cell lung cancer who have failed one prior platinum-containing line. *Future Oncol.* 2019;15(3):231–239.

sensitivity cohorts exceeded the average case-weighted threshold amount by $126,610, $112,396, $75,948, and $73,592 respectively. Because the final inflated average case-weighted standardized charge per case exceeds in all scenarios the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

While we would not expect a significant difference, we noted in the proposed rule that instead of referring to the correction notice tab within the FY 2022 New Technology Thresholds data file, the applicant referred to the final rule tab. The FY 2022 New Technology Thresholds data file is available on the CMS IPPS home page at: *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page#Data.*

We also noted that the analysis provided by the applicant includes many MS–DRGs that are defined by factors that may or may not be related to ZEPZELCA™'s indication for metastatic SCLC. For example, it is not clear that MS–DRG 004 Trach w MV >96 Hrs or Pdx Exc Face, Mouth & Neck w/o Maj O.R has a direct connection to small cell lung cancer though it may be related.

We invited public comment on whether ZEPZELCA™ meets the cost criterion.

Comment: The applicant submitted a comment in response to these concerns. First, with respect to the MS–DRGs that were selected, the applicant clarified that in conducting the cost criterion analysis for the primary cohort, it identified patients that would best represent candidates for ZEPZELCA™, without regard to MS–DRG assignment. The applicant further stated that there is no ICD–10–CM diagnosis code specific to SCLC, only C34—malignant neoplasm of bronchus and lung and as such, the applicant believes that ZEPZELCA™ candidates would have a principal diagnosis of Malignant Neoplasm of Bronchus and Lung and receive chemotherapy during the hospital stay. Per the applicant, the top 4 MS–DRGs within the primary cohort were DRG 180 RESPIRATORY NEOPLASMS WITH MCC, DRG 181 RESPIRATORY NEOPLASMS WITH CC, DRG 166—OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH MCC, and DRG 167—OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH CC. The applicant stated that these 4 MS–DRGs represent almost 81 percent of all cases in the ZEPZELCA™ primary cohort but acknowledges that some of the MS–DRGs are atypical MS–DRGs for SCLC patients. Per the applicant, all cases had a principal diagnosis of Malignant Neoplasm of Bronchus and Lung and received chemotherapy during the hospital stay. The applicant stated that these atypical MS–DRGs may have appeared because of complications and other factors that drive MS–DRG assignment but that these complications alone would not render the inclusion of these MS–DRGs inappropriate. The applicant further noted that the MS–DRGs referenced by CMS represent a small share of all cases (for example, MS–DRG 004 accounts for 1 percent of the full primary cohort) and that if deemed appropriate, excluding certain MS–DRGs from the cost analysis would not impact the cost criterion results as virtually all individual MS–DRGs have standardized charges that exceed the cost criterion threshold. The applicant concluded by stating that ZEPZELCA™ meets the cost criterion in the primary and three sensitivity cohort analyses.

Next, the applicant indicated that it performed an analysis on a primary cohort and three sensitivity cohorts. Per the applicant, the primary cohort included inpatient hospital stays with the principal diagnosis code Malignant neoplasm of bronchus and lung (ICD–10–CM C34xx) and the patient received chemotherapy, as determined by presence of an ICD–10–CM Z51.11 (Encounter for antineoplastic chemotherapy), ICD–10–CM Z51.12 (Encounter for antineoplastic immunotherapy), or any ICD–10–PCS chemotherapy code on the claim. The applicant also reported its results from the three sensitivity cohorts.

Finally, with respect to referencing the correction notice tab within the FY 2022 New Technology Threshold data file, the applicant stated that it re-evaluated the cost criterion for the primary and 3 sensitivity cohorts using the correction notice thresholds and did not find material difference in the threshold or cost criterion findings. Specifically, the applicant identified the average case-weighted threshold amount for the primary cohort as $79,439, and $70,505, $70,245, and $57,384 for sensitivity cohorts 1, 2 and 3, respectively. The applicant stated the final inflated average case-weighted standardized charge per case in the primary cohort and three sensitivity cohorts exceeded the average case-weighted threshold amount by $126,591, $112,390, $75,929, and $73,591 respectively.

Response: We appreciate the applicant's clarification regarding the MS–DRGs included in the analysis and agree that atypical DRGs represent a small share of all cases. Because virtually all individual MS–DRGs have standardized charges that exceed the cost criterion threshold we believe that the applicant has sufficiently addressed this concern. Based on the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for ZEPZELCA™, as discussed in the proposed rule (86 FR 25355 through 25356) and previously summarized, and consideration of the comment received, we agree the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in each of the primary and 3 sensitivity cohorts. Therefore, ZEPZELCA™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that ZEPZELCA™ significantly improves clinical outcomes over existing treatment options for adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy in five ways. First, ZEPZELCA™ offers an improved treatment option from both a safety and efficacy standpoint. Second, ZEPZELCA™ offers safety improvement for treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy over safety results previously reported in the literature for a comparable patient population. Third, patients with metastatic SCLC whose disease progresses on or after platinum-based chemotherapy achieved higher overall response rates (ORRs) following treatment with ZEPZELCA™ than ORR that had been previously reported in the literature for a comparable patient population. Fourth, overall survival (OS) rates achieved with ZEPZELCA™ are clinically meaningful and are the highest rates reported for patients with metastatic SCLC whose disease progresses on or after platinum-based chemotherapy in more than 2 decades. Fifth, the applicant asserted that ZEPZELCA™ may represent a valuable treatment alternative to platinum rechallenge. The applicant submitted (or in some cases, referred to) multiple sources in support of these claims including retrospective analyses and other studies, a meta-analysis, data abstracts, literature reviews, prescribing information, FDA approved cancer therapies, practice guidelines, workgroup deliberations, a commentary, and an opinion regarding survival outcomes.

With regard to the first claim, the applicant stated that ZEPZELCA™ is the first second-line treatment option approved for SCLC since 1998 and is indicated for the treatment of adult

patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy, a patient population with dismal outcomes. The applicant also stated that ZEPZELCA™ offers an improved treatment option from both a safety and efficacy standpoint. The applicant outlined the nature of small cell lung cancer, patient treatment and prognosis. The applicant also stated that ZEPZELCA™ could represent a valuable option for a patient population with high unmet medical need.[684] Specifically, the applicant referred to four analyses, an epidemiology review, prescribing information, practice guidelines, a literature review inclusive of four articles, and one ZEPZELCA™ study.

First, an analysis stated that although small cell lung cancer shows high sensitivity to first-line chemotherapy and radiotherapy, most patients develop disease relapse or progression.[685] Another analysis stated that most patients experience relapse of small cell lung cancer within 1 year of treatment.[686] A separate analysis indicated that most patients who have initially responded to chemotherapy and radiotherapy eventually experience recurrence of the cancer in a few months.[687] The fourth analysis indicated that almost all patients with extended disease will develop disease relapse or progression after first-line treatment and that without second-line chemotherapy, the median survival time is 2 to 4 months.[688]

Next, in referring to the epidemiology review, the applicant stated that most cases of small cell lung cancer occur in individuals aged 60–80.[689] In referring to prescribing information, the applicant stated that in 1998, Hycamtin (topotecan) was approved for patients with SCLC sensitive disease after failure of first-line chemotherapy. The applicant further stated that in the topotecan Phase 3 clinical study, sensitive disease was defined as disease responding to chemotherapy, but subsequently progressing at least 60 days after chemotherapy.[690]

Next, in referring to practice guidelines, the applicant stated that ZEPZELCA was studied in a broader (resistant disease and sensitive disease) population of SCLC patients and that prespecified subgroup analyses of ZEPZELCA results were done for patients with SCLC by CTFI in patients with resistant disease (CTFI <90 days) and sensitive disease (CTFI interval ≥90 days). The applicant further noted that NCCN guidelines list ZEPZELCA as a preferred regimen for second-line treatment of patients with a CTFI ≤6 months and recommended ZEPZELCA for patients with a CTFI >6 months.[691]

Next, the applicant referred to a literature review and submitted four sources. First, per the applicant, Iams et. al. describes available data on clinical efficacy, the emerging evidence regarding biomarkers and ongoing clinical trials using immune checkpoint inhibitors and other immunotherapies in patients with SCLC. The article included a discussion of the significant unmet needs in second-line therapy for SCLC.[692] Second, per the applicant, Tsiouprou et. al. reported on a literature review of immunotherapy in treatment of ES–SCLC and included a discussion of the significant unmet needs in second-line therapy for SCLC.[693] Third, per the applicant, Wang et. al. presented a review of SCLC development, current therapy and included a discussion of the significant unmet needs in second-line therapy for SCLC.[694] Fourth, per the applicant, Taniguchi et. al., is an opinion article discussing recent developments in the treatment of SCLC and includes a discussion of the significant unmet needs in second-line therapy for SCLC.[695]

Finally, the applicant referred to Trigo, et. al., and stated that authors expressed that ZEPZELCA could present a valuable potential new treatment option after first-line platinum-based chemotherapy.[696]

With regard to the second claim, the applicant asserted that ZEPZELCA™ offers safety improvement for treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy over safety results previously reported in the literature for a comparable patient population. The applicant asserted that safety is of particular importance for patients > 65 with age being a major patient-related risk factor.[697] The applicant also referred to a meeting abstract stating that several acute comorbidities were more common in Medicare patients initiating second-line chemotherapy than in all patients at diagnosis: infectious disease (57% versus 43%), electrolyte disorder (50% versus 22%), anemia (45% versus 19%), neutropenia (17% versus 0.1%), thrombocytopenia (12% versus 2%), and diarrhea (7% versus 3%).[698]

The applicant also referred to six studies to support this claim. First, the applicant submitted Trigo et. al., that was based on Study B–005 (NCT01454972), a single-arm, open label, phase II basket trial to evaluate the activity and safety of lurbinectedin in patients with SCLC after failure of platinum-based chemotherapy. One hundred five patients with a diagnosis of SCLC and pre-treated with only one previous chemotherapy-containing line of treatment were included. Treatment consisted of 3.2mg/m2 lurbinectedin intravenously every 3 weeks until disease progression or unacceptable toxicity. The safety-related outcomes demonstrated the following adverse events: anemia 9%, leucopenia 29%, neutropenia 46%, and thrombocytopenia 7%. Serious treatment-related adverse events occurred in 10% of patients, of which neutropenia and febrile neutropenia

[684] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470–2045*.

[685] Shiozawa, T. Rechallenge with first-line platinum chemotherapy for sensitive-relapsed small-cell lung cancer. *Case Rep Oncol.* 2018;11:622–632.

[686] Naito Y, et al. Rechallenge treatment with a platinum-based regimen in patients with sensitive relapsed small-cell lung cancer. *Medical Oncology* (2018) 35:61.

[687] Horita N, et al. Topotecan for relapsed small-cell lung cancer: systematic review and meta-analysis of 1347 patients. *Sci Rep* 2015;5: 15437.

[688] Wakuda K et al. Efficacy of second-line chemotherapy in patients with sensitive relapsed small-cell lung cancer. *In vivo.* 33:2229–2234 (2019).

[689] Tan WT, et al. Small Cell Lung Cancer (SCLC), Medscape, Oncology. Updated June 19, 2020. Emedicine.medscape.com.

[690] FDA website, Hycamtin (topotecan) prescribing information., Rev. 2/2014: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022453s002lbl.pdf* .

[691] NCCN Clinical Practice Guidelines in Oncology, Small Cell Lung Cancer. Version 4.2020, July 7, 2020. *https://nccn.org*.

[692] Iams WT, et al. Immunotherapeutic approaches for small-cell lung cancer. *Nat Rev Clin Oncol.* 2020 May; 17(5):300–312. doi: 10.1038/s41571–019–0316-z. Epub 2020 Feb 13.

[693] Tsiouprou I, et al. The rôle of immunotherapy in extensive stage small-cell lung cancer: a review of the literature. *Can Respir J.* 2019 Nov 3;2019:6860432. doi: 10.1155/2019/6860432. eCollection 2019.

[694] Wang Y, et al. New insights into small-cell lung cancer development and therapy. *Cell Biol Int.* 2020 Aug;44(8):1564–1576. doi: 10.1002/cbin.11359. Epub 2020 Apr 18.

[695] Taniguchi H, et al. Targeted therapies and biomarkers in small cell lung cancer. *Front Oncol.* 2020 May 20;10:741. doi: 10.3389/fonc.2020.00741. eCollection 2020.

[696] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470–2045*.

[697] Simeone E, et al. Nivolumab for the treatment of small cell lung cancer. *Exp Rev Resp Med.* 2020;14(1):5–13.

[698] Danese M, et al. Comorbidity in patients with extensive disease small cell lung cancer. Presented at the AMCP Managed Care & Specialty Pharmacy Annual Meeting; March 27–30, 2017; Denver, CO.

were the most common with 5% of patients for each.[699]

Second, the applicant submitted an article from Von Pawel, et. al., of a randomized phase 3 study of a total of 637 patients with refractory or sensitive SCLC treated with topotecan and reported hematologic toxicities of grade ≥3 anemia, 30.5%; neutropenia, 53.8%; thrombocytopenia, 54.3%; febrile neutropenia, 3%.[700]

Third, the applicant submitted an open label phase 2 study of 179 patients with SCLC who relapsed after initial platinum-based chemotherapy, treated with topotecan and reported hematologic toxicities of neutropenia, 78.4%; thrombocytopenia, 45.5%; and febrile neutropenia/neutropenic infection/neutropenic sepsis, 18%.[701]

Fourth, the applicant submitted an abstract from Monnet, et. al. of an open-label, multicenter, phase 3 trial that randomized patients with SCLC that responded to first-line platin-etoposide doublet treatment but showed evidence of disease relapse or progression at least 90 days after completion of the first-line treatment. Eighty-two patients were assigned to each treatment group: Those receiving combination chemotherapy (carboplatin and etoposide) versus those receiving oral topotecan. The abstract indicated that grade ¾ neutropenia was significantly more common in the topotecan group at 35.8% versus 19.7%; insignificantly more febrile neutropenia in the topotecan arm at 13.6% versus 6.2%; no difference for grade ¾ thrombocytopenia, 35.8% versus 30.9%; and anemia, 24.6% versus 21%.[702]

Fifth, the applicant submitted an abstract from Leary, et. al., that is described as a pooled safety analysis with data from the phase II, single arm basket study by Trigo, et. al. (discussed previously), and a phase III RCT, the CORAIL study. The pooled analysis included a total of 554 patients treated with lurbinectedin. Of the 554, 335 were from the phase II basket study with selected solid tumors (9 indications including 105 patients with small cell lung cancer) and 219 were from the phase III CORAIL study with platinum resistant ovarian cancer. Authors presented an indirect exploratory comparison (pooled data from CORAIL + basket) and a direct comparison (data from CORAIL) of lurbinectedin vs. topotecan. Authors reported adverse events with lurbinectedin were grade ½ fatigue, nausea and vomiting. Treatment-related lurbinectedin/topotecan outcomes showed: dose reductions: 22.9/48.3%; delays: 25.8/52.9%; grade ≥3 serious adverse events: 15.0/32.2%; discontinuations: 3.2/5.7%; deaths: 1.3/1.5%; granulocyte colony stimulating factor (G–CSF) use: 23.8/70.1%; and transfusions: 15.9/52.9%. Authors concluded by stating that a significant safety advantage was observed when lurbinectedin was compared with topotecan in the CORAIL trial in terms of hematological toxicities. Authors also noted that with the limitations of indirect comparisons, in the pooled safety analysis, fewer lurbinectedin-treated patients had severe hematological toxicities, severe adverse events, dose adjustments, treatment discontinuations and use of supportive treatments than topotecan-treated patients.[703]

Sixth, the applicant provided a presentation summarizing results from the randomized phase 3 CORAIL study. The patient population was comprised of platinum resistant ovarian, fallopian or primary peritoneal cancer. Enrolled patients were randomly assigned to receive lurbinectedin or investigator choice of pegylated liposomal doxorubicin (PLD) or topotecan. The applicant stated that ZEPZELCA™ was better tolerated than the control arm and that, overall, the data support a favorable safety profile for ZEPZELCA™.[704]

With regard to the third claim, the applicant stated that patients with metastatic SCLC whose disease progresses on or after platinum-based chemotherapy achieved higher ORRs following treatment with ZEPZELCA™ than ORR that had been previously reported in the literature for a comparable patient population. The applicant referred to four primary resources in support of ZEPZELCA™. First, as described previously, the applicant submitted Trigo, et. al., in which the primary endpoint is described as lurbinectedin anti-tumor activity in terms of investigator-assessed overall response (OR) and duration of response (DOR) as a secondary endpoint.[705] The OR rate was identified as 35.2% and the mean DOR as 5.3 months. Second, the applicant submitted an abstract from Subbiah, et. al., a sub-study from Study B–005, that concluded that time from randomization to response was similar regardless of prior resistance or sensitivity to platinum-based chemotherapy, and clinically meaningful DOR was noted in both subgroups of responders. [706] Third, the applicant submitted an abstract from a second sub-study from Study B–005, indicating that ORR was similar across baseline characteristics: Age <65 = 36.8%; age >65 = 32.4%; female = 31%; male = 38.1%; 1 prior line of therapy = 34.7%; >2 prior lines of therapy = 42.9%; BSA 1.8m2 = 34.5%; and BSA >1.8m2 = 36%. The authors concluded by noting that response to lurbinectedin appeared consistent regardless of baseline patient characteristics.[707] Fourth, the applicant submitted a commentary from Arrieta, et. al., and stated that ZEPZELCA™ outperformed all previously reported results for topotecan.[708]

The applicant also referred to three additional sources reflecting ORRs following treatment with topotecan. The Phase 3 trial of a total of 637 patients with refractory or sensitive SCLC treated with topotecan demonstrated an ORR of 16.9% and DOR of 4.2 months.[709] In the open-label, multicenter, phase 3 trial of 164 patients with sensitive relapsed SCLC that responded to first-line platin etoposide doublet treatment but showed evidence of disease relapse or progression at least 90 days after completion of the first-line treatment,

[699] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470–2045.*

[700] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[701] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

[702] Monnet, 2 L., et. al. Carboplatin-Etoposide Versus Topotecan as Second-Line Treatment for Sensitive Relapsed Small-Cell Lung Cancer: Phase 3 Trial. Journal of Thoracic Oncology Vol. 14 No. 10S.

[703] Leary A, et al. Pooled safety analysis of single-agent lurbinectedin versus topotecan (Results from a randomized phase III trial CORAIL and a phase II basket trial). ASCO2020 (American Society of Oncology); May 29–31, 2020. Abstract and poster.

[704] Gaillard S, et al. Phase III trial of lurbinectedin versus PLD or topotecan in platinum-resistant ovarian cancer patients: results of the CORAIL trial. 2018 ESMO Presentation

[705] Additional secondary endpoints are discussed with the overall survival claim.

[706] Subbiah V, et al. Phase 2 basket trial of lurbinectedin in second-line SCLC: Characteristics and outcomes in treatment responders. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[707] Sands J, et al. Phase 2 basket trial of lurbinectedin in small-cell lung cancer (SCLC): Analysis of efficacy by baseline characteristics. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[708] Arrieta O, et al. New opportunities in a challenging disease: lurbinectedin for relapsed small-cell lung cancer. Comment in *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020..*https://doi.org/10.1016/S1470–2045(20)30097–8.*

[709] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

patients randomized to the topotecan group demonstrated an ORR of 25%.[710] Lastly, a randomized, multi-center phase 3 trial of 107 patients treated with topotecan reported an ORR of 24.3%.[711]

With regard to the fourth claim, the applicant stated that the OS rates achieved with ZEPZELCA™ are clinically meaningful and are the highest rates reported for patients with metastatic SCLC whose disease progresses on or after platinum-based chemotherapy in more than 2 decades. The applicant submitted two studies in support of its claim of improved survival rates in patients treated with ZEPZELCA™. First, as described previously, the applicant submitted Trigo, et. al. and highlighted secondary endpoints including progression-free survival, progression-free survival at 4 and 6 months, overall survival and overall survival at 6 and 12 months. The mean progression free survival was identified as 3.5 months, mean overall survival 9.3 months in the overall population, 11.9 months in patients with a CTFI ≥90 days and 5.0 months in those with CTFI <90 days.[712]

Second, the applicant submitted an abstract from Subbiah, et. al., that summarized a sub-study from Study B–005 in which overall survival was a secondary endpoint. Authors report that patients treated with lurbinectedin had CTFI ≥180 days and form the basis for their analysis. Sixty percent of patients were male, had ECOG PS 0–1, and had a median age of 57 years. Extensive stage disease at initial diagnosis was present in 35% of patients. All 20 patients had received prior platinum/etoposide, with no prior immunotherapy. Authors also reported that with a censoring of 55.0%, the median overall survival was 16.2 months. Per the abstract, eleven patients (55.0%) were censored for survival analysis: Eight were on follow-up after disease progression, two were ongoing lurbinectedin treatment, and one had treatment discontinuation because of a treatment-related adverse event (worsening of prior peripheral neuropathy). Median follow-up was 15.6 months. Authors concluded time from randomization to response was similar regardless of prior resistance or sensitivity to platinum-based chemotherapy.[713]

The applicant also referred to several randomized phase I and II studies of patients undergoing alternate therapies and highlighted those OS rates. The applicant provided an abstract from Monnet, et. al., (as mentioned previously with respect to applicant's second and third claims) summarizing results from a study that investigated whether the doublet carboplatin-etoposide was superior to topotecan monotherapy as second-line treatment in patients with sensitive relapsed SCLC. Authors reported patients treated with topotecan had progression free survival (PFS) of 2.7 months and OS of 7.4 months.[714] The applicant also referred to Evans, et. al., summarizing results from a study of patients with SCLC who relapsed after initial platinum-based chemotherapy who were divided into subgroups, chemosensitive vs. chemo-resistant/refractory disease. Patients were treated with topotecan. Authors reported topotecan PFS of 3.0 months and OS of 6.8 months.[715] The applicant referred to Von Pawel, et. al., summarizing the results of a phase 3 trial of a total of 637 patients with refractory or sensitive SCLC, including topotecan PFS of 3.5 months and OS of 7.8 months (5.7 months for refractory).[716] Lastly, the applicant referred to Von Pawel, et. al., that reported randomized, multi-center phase 3 results for topotecan with time to progression of 13.3 weeks and median OS of 25 weeks.[717]

The applicant explained that a statement from an American Society of Clinical Oncology (ASCO) workgroup indicated that relative improvements in median OS of at least 20% are necessary to define a clinically meaningful improvement in outcome.[718] The applicant summarized oncology literature reviews between 2014 and 2016 asserting that ASCO's threshold for OS was met in only 12% of studies (6 of 49) and 19% of therapies.[719] [720]

The applicant further stated that ZEPZELCA™'s median OS for the overall population compared to the literature, meets the ASCO threshold and, for subsets of patient groups, median OS exceeds the ASCO threshold for clinically meaningful.

The applicant concluded by stating that there is an urgent need for new treatment options for the SCLC population.[721] The applicant asserted that CMS's new technology add-on payment approval of TECENTRIQ® for the treatment of patients with ES–SCLC effective for FY 2021 (85 FR 58684) further supports the urgency, referring to its 2 month improvement in survival.

The applicant also referred to comments from specialists in the field of lung cancer stating that despite small trial sizes, improvement in overall survival is a major achievement and that any advance in survival is important given that few patients diagnosed with SCLC survive for even a year despite treatment.[722]

With regard to the fifth claim, that ZEPZELCA™ may represent a valuable treatment alternative to platinum rechallenge, the applicant submitted several sources pertaining to ZEPZELCA™. First, the applicant submitted two sub-analyses from Subbiah, et al., that were based on Study B–005 as its primary support for ZEPZELCA™. In both of these sub-analyses, patients had been pre-treated with one prior platinum-containing line. The first analysis included 20 patients from a subset of patients with CTFI >180 and authors report that patients treated with lurbinectedin had an ORR

[710] Monnet, 2 L., et. al. Carboplatin-Etoposide Versus Topotecan as Second-Line Treatment for Sensitive Relapsed Small-Cell Lung Cancer: Phase 3 Trial. Journal of Thoracic Oncology Vol. 14 No. 10S

[711] Von Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol.* Vol 17, No 2, 1999: 658–667.

[712] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470–2045.*

[713] Subbiah V, et al. Activity of lurbinectedin in second-line SCLC patients who are candidates for platinum rechallenge IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[714] Monnet, 2 L., et. al. Carboplatin-Etoposide Versus Topotecan as Second-Line Treatment for Sensitive Relapsed Small-Cell Lung Cancer: Phase 3 Trial. Journal of Thoracic Oncology Vol. 14 No. 10S

[715] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

[716] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[717] Von Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol.* Vol 17, No 2, 1999: 658–667.

[718] Ellis LM, et al. American Society of Clinical Oncology perspective: raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol.* 2014;32(12:1277–1280.

[719] Dreicer JJ, et al. Clinically meaningful benefit: real world use compared against the American and European guidelines. *Blood Cancer Journal.* 7,10.1038/s41408–017–0009–8.

[720] Kumar H, et al. An appraisal of clinically meaningful outcomes guidelines for oncology clinical trials, *JAMA Oncology*. Published online: Vol 2, No 9, 1238–1240.

[721] NCI Staff. For small cell lung cancer, immunotherapy drug finally brings improved survival. National Cancer Institute. October 3, 2018. *https://www.cancer.gov/news-events/cancer-currents-blog/2018/small-cell-lung-cancer-atezolizumab-survival.*

[722] NCI Staff. For small cell lung cancer, immunotherapy drug finally brings improved survival. National Cancer Institute. October 3, 2018. *https://www.cancer.gov/news-events/cancer-currents-blog/2018/small-cell-lung-cancer-atezolizumab-survival.*

at 60.0% and a median DoR of 5.5 months. The second analysis included 60 patients from a SCLC cohort of the basket trial, with CTFI >90 d (20 pts with CTFI >180 d). The applicant states that ZEPZELCA™ was shown to be effective and well-tolerated in the platinum-sensitive relapsed SCLC population especially when CTFI >180 days. From these results, the authors concluded that ZEPZELCA™ may represent a valuable alternative to platinum rechallenge.[723] [724] The applicant also referenced Arrieta et al., stating that ZEPZELCA™ data outperformed less established treatment schemes including platinum rechallenge.[725] The applicant stated that the July 7, 2020 NCCN Clinical Practice Guidelines in Oncology indicate that lurbinectedin is identified as a Preferred Regimen in relapse ≤6 months and a Recommended Regimen in relapse >6 months.[726] The applicant referred to the authors' conclusion in Genestreti et al., stating that the outcome for second line chemotherapy for SCLC is poor and that rechallenge platinum/etoposide is a reasonable option with potentially better outcomes than standard chemotherapy.[727]

Finally, the applicant referred to Monnet, et al., stating that patients treated with combination therapy, carboplatin and etoposide, achieved a median OS of 7.4 months and ORR of 49%.[728]

In the proposed rule (86 FR 25360), we noted the following concerns. The evidence submitted by the applicant in support of ZEPZELCA™'s improvement in overall response and survival rates was based on one single-arm, open label, phase II basket study (Study B–005 (NCT01454972)) and several smaller subsetted analyses that were based on the basket study, and we noted that without a direct comparison arm it may be more difficult to draw definitive conclusions.[729] [730] [731] [732] We noted the following differences between the historical control patients and patients treated with ZEPZELCA™ in these studies, which may confound the comparisons: First, patients with central nervous system involvement (brain metastases) were excluded from ZEPZELCA™ treatment, and we noted that Arrieta, et al., noted that this criterion is of particular interest when translating results to the clinical setting, since patients with SCLC are known to be prone to develop brain metastases, and up to 50% do so throughout the disease course.[733] Second, patients treated with ZEPZELCA™ had access to immunotherapy during first line treatment, which may support patients' immune systems in fighting cancer. Third, the CTFI used in the single arm basket trial differed from those used in the historical controls of topotecan studies, and we noted that CTFIs can impact treatment response and outcome. As, per the applicant, ZEPZELCA™ was listed as a preferred regimen by the NCCN Clinical Practice Guidelines for second-line treatment of patients with a CTFI ≤6 months and recommended for patients with a CTFI >6 months, while topotecan is only FDA approved for chemotherapy-sensitive cases, defined using a 60 day CTFI, we noted that the appropriate comparator treatment for ZEPZELCA™ would differ depending on the CTFI subset. However, the historical controls relied on an overall topotecan population with CTFI >60. To the extent that this group was more heavily weighted with patients in the lower CTFI group, it was unclear whether this may partially explain the poorer outcomes of patients in the historical control groups. We also noted that, while the claim of improved hematological outcomes using ZEPZELCA™ appeared to be mostly supported by the female-only arm of the CORAIL study, results from the pooled sample of the basket trial still appeared to demonstrate an improvement over the topotecan arm. We believed that this may suggest that the inclusion of male patients did not alter the conclusion that patients treated with ZEPZELCA™ appeared more favorable than those treated with topotecan. We further noted that bone marrow stimulating drugs were allowed in the topotecan arm of the CORAIL study so the observed adverse hematologic effects may have been the best case for that arm of the study. Finally, we noted that the subsetted analyses generated from the primary basket study had small sample sizes and the authors of these studies stated that further research on larger populations is required to draw firm conclusions.[734] [735]

We invited public comments on whether ZEPZELCA™ meets the substantial clinical improvement criterion.

Comment: The applicant submitted comments in response to CMS' concerns pertaining to substantial clinical improvement. First, with respect to the concern that the evidence submitted by the applicant was based on one single-arm, open label, phase II basket study (Study B–005 (NCT01454972) and several smaller subsetted analyses, the applicant stated that the basket study evaluated ZEPZELCA™ as a single-agent in patient cohorts across 9 different tumor types (a basket trial design), including a cohort of patients with SCLC with disease progression on or after platinum-based chemotherapy (n=105) (NCT02454972), conducted at 26 investigational sites in the European Union, United Kingdom and U.S. The applicant stated that the study was originally intended to be a signal-finding study, was designed as a single-arm trial, and the overall response rate (ORR) in the SCLC cohort, which consisted of patients who had received a prior line of chemotherapy, was

[723] Subbiah V, et al. Activity of lurbinectedin in second-line SCLC patients who are candidates for platinum rechallenge IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[724] Subbiah V, et al. Activity in second-line SCLC patient candidates for platinum rechallenge. ESMO (European Society for Medical Oncology) 2020 Congress; September 19–21, 2020. Poster 1784P.

[725] Arrieta O, et al. New opportunities in a challenging disease: lurbinectedin for relapsed small-cell lung cancer. Comment in *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020 . . . *https://doi.org/10.1016/S1470–2045(20)30097–8*.

[726] NCCN Clinical Practice Guidelines in Oncology, Small Cell Lung Cancer. Version 4.2020, July 7, 2020. *https://nccn.org*.

[727] Genestreti G, et al. Outcomes of platinum-sensitive small-cell lung cancer patients treated with platinum/etoposide rechallenge: a multi-institutional retrospective analysis. *Clinical Lung Cancer,* Vol. 16, No. 6, e223–8.

[728] Monnet, 2 L., et al. Carboplatin-Etoposide Versus Topotecan as Second-Line Treatment for Sensitive Relapsed Small-Cell Lung Cancer: Phase 3 Trial. Journal of Thoracic Oncology Vol. 14 No. 10S

[729] Sands J, et al. Phase 2 basket trial of lurbinectedin in small-cell lung cancer (SCLC): Analysis of efficacy by baseline characteristics. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[730] Subbiah V, et al. Phase 2 basket trial of lurbinectedin in second-line SCLC: Characteristics and outcomes in treatment responders. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[731] Subbiah V, et al. Activity of lurbinectedin in second-line SCLC patients who are candidates for platinum rechallenge IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[732] Subbiah V, et al. Activity in second-line SCLC patient candidates for platinum rechallenge. ESMO (European Society for Medical Oncology) 2020 Congress; September 19–21, 2020. Poster 1784P.

[733] Arrieta O, et al. New opportunities in a challenging disease: lurbinectedin for relapsed small-cell lung cancer. Comment in *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020 . . . *https://doi.org/10.1016/S1470–2045(20)30097–8*.

[734] Subbiah V, et al. Activity in second-line SCLC patient candidates for platinum rechallenge. ESMO (European Society for Medical Oncology) 2020 Congress; September 19–21, 2020. Poster 1784P.

[735] Sands J, et al. Phase 2 basket trial of lurbinectedin in small-cell lung cancer (SCLC): Analysis of efficacy by baseline characteristics. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

notable at 35 percent.[736] The applicant further noted that based on the study ORR and duration of response in the SCLC cohort, the FDA granted accelerated approval of ZEPZELCA™ to allow for earlier approval of drugs that treat serious conditions and that fill an unmet medical need based on a surrogate endpoint (ORR and duration of response) that is thought to predict clinical benefit. The applicant stated that continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Per the applicant, accelerated approval of ZEPZELCA™ is of paramount importance to metastatic SCLC patients given the high relapse and disease progression rates in SCLC2–5 and because no second-line therapy options had been approved in over 20 years (that is, topotecan in 1998). The applicant stated that because most cases of SCLC occur in individuals aged 60–80 years,[737] this is a risk-benefit profile that warrants additional second-line treatment options and that ZEPZELCA™ fulfills a high unmet need for patients with metastatic SCLC, with a majority being Medicare beneficiaries.

Next, with respect to the differences between the historical control patients and patients treated with ZEPZELCA™ in these studies, the applicant stated that while SCLC patients often develop brain metastases, it is common for clinical trials in SCLC to exclude patients with central nervous system (CNS) involvement, including the Phase 3 trial for amrubicin versus topotecan, where patients with prior brain metastasis and symptomatic CNS metastases were excluded.[738] Per the applicant, such exclusions are in part due to the poor clinical status of these patients. The applicant stated that in Study B–005, there were 4 patients that had CNS involvement (3 patients had a history of CNS involvement, and 1 patient had CNS involvement at baseline (protocol deviation)). The applicant also stated that among these 4 patients treated with ZEPZELCA™, there were 2 partial responses, 1 stable disease, and 1 progressive disease (data on file).

With respect to the concern that patients treated with ZEPZELCA™ had access to immunotherapy during first line treatment, the applicant stated that Study B–005 was initiated prior to the FDA approval of immunotherapy agents such as atezolizumab, nivolumab, and durvalumab. The applicant also stated that in total, only 8 of the 105 patients enrolled were previously treated with immunotherapy. Per the applicant, in reviewing the data in the small number of patients that fell into this category, it could not determine that these patients were driving the median overall response. The applicant stated that the median OS 95% confidence interval of the 105 patients is overlapping with the 95% confidence interval of the 97 patients who were not treated with immunotherapy (data on file).

With respect to the concern that the CTFI used in the single arm basket trial differs from those used in the historical controls of topotecan studies, the applicant stated that while it is possible that grouping by CTFI may affect efficacy measures, it is important to understand that the clinical community uses different CTFI groups with no singular convention. Per the applicant, some in the oncology community use 90 days as a cutoff (concordant with European Society for Medical Oncology (ESMO)), and others use 180 days (concordant with NCCN guidelines). The applicant stated that the study that led to the FDA approval of topotecan used 60 days as a CTFI cutoff; [739] Study B–005 used 90 days. Per the applicant, Study B–005 also included a population that was actually sicker than populations in several SCLC studies because of the inclusion of patients who had CTFI <30 days (n=21 of 105 patients). In order to demonstrate a more specific comparison with the topotecan trial that led to its FDA approval, an exploratory analysis was conducted excluding patients with CTFI <60 from the Study B–005 results. The applicant stated that this analysis supports that when matching CTFI groupings for comparison purposes, the efficacy profile of ZEPZELCA™ is substantially improved over study results that Van Pawel et. al.[740] reported for topotecan.

With respect to the concern that improved hematological outcomes using ZEPZELCA™ appears to be mostly supported by the female-only arm of the CORAIL study, the applicant stated that a significant safety advantage was observed when ZEPZELCA™ was compared with topotecan in the CORAIL trial in terms of hematological toxicities. Per the applicant, this finding was based on an indirect exploratory comparison (pooled data from CORAIL + Study B–005) and a direct comparison (data from CORAIL).[741] The applicant stated that the inclusion of male patients in the pooled safety analysis did not alter the conclusion that patients treated with ZEPZELCA™ appeared more favorable than those treated with topotecan.

With respect to the concern regarding bone marrow stimulating drugs, the applicant stated that bone marrow stimulating drugs were allowed in the topotecan arm of the CORAIL study so the observed adverse hematologic effects may have been the best case for that arm of the study, concurring with CMS' observations. The applicant reiterated that a significant safety advantage was observed when ZEPZELCA™ was compared with topotecan in the CORAIL trial and in terms of hematological toxicities based on indirect exploratory comparison (pooled data from CORAIL + Study B–005) and a direct comparison (data from CORAIL).[742] Per the applicant, inclusion of male patients in the pooled safety analysis did not alter the conclusion that patients treated with ZEPZELCA™ appeared more favorable than those treated with topotecan.

Finally, with respect to the concern that the subsetted analyses generated from the primary basket study have small sample sizes, the applicant stated that while the subset sizes are small in number, these are actually sizable for a rare disease such as SCLC. Per the applicant, it is standard practice for study investigators and authors to conclude that further research is needed when presenting study results but that subset analyses can provide extremely meaningful clinical findings for consideration when clinicians evaluate and make real-world treatment decisions. The applicant stated that ZEPZELCA™ may represent a valuable clinical option to platinum rechallenge. Per the applicant, the results of this post-hoc analysis were recently published in December 2020 by Subbiah et. al. in the peer-reviewed journal, Lung Cancer,[743] showing that Study B–

[736] Naito Y, et al. Rechallenge treatment with a platinum-based regimen in patients with sensitive relapsed small-cell lung cancer. Medical Oncology (2018) 35:61.

[737] Tan WT, et al. Small Cell Lung Cancer (SCLC), Medscape, Oncology. Updated June 19, 2020. Emedicine.medscape.com

[738] von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line therapy in small cell lung cancer. J Clin Oncol. Vol 32, No 35, 2014: 4012–4020.

[739] von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line therapy in small cell lung cancer. J Clin Oncol. Vol 32, No 35, 2014: 4012–4020

[740] von Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. J Clin Oncol. Vol 17, No 2, 1999: 658–667.

[741] Leary A, et al. Pooled safety analysis of single-agent lurbinectedin versus topotecan (Results from a randomized phase III trial CORAIL and a phase II Basket trial). ASCO2020 (American Society of Oncology); May 29–31, 2020. Abstract and poster.

[742] Ibid

[743] von Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for

Continued

005 patients with CTFI >180 days (n=20) achieved a 60% ORR (Table 23 of the New Technology Add-on Payment application), which compares favorably to the ORR of 46% (n=11) in a previous platinum-rechallenge study sub-group analysis reported by Wakuda et. al.[744] Per the applicant, overall survival in the Study B–005 post-hoc analysis in patients with CTFI <180 days was 16.2 months (Table 23), which compares favorably to that reported by Wakuda et al, 15.7 months (n=11).[745] The applicant stated that while the CTFI >180 days cohort was small, it represented nearly 20% of the Study B–005 SCLC trial population and demonstrated high ORR and overall survival that appears in line with clinical efficacy of platinum rechallenge. The applicant concluded by stating that these findings are now informing clinical practice in the treatment of SCLC.

We also received several comments from clinicians in the fields of oncology and pharmacy, stating that the rapid spread of SCLC and early relapse after first-line treatment make management of this disease very challenging. The commenters stated that ZEPZELCA™ is effective in the treatment of relapsed SCLC, fills an unmet need in second line treatment, is easy to administer and is well tolerated. Commenters stated that approving ZEPZELCA™ for new technology add-on payments would expedite care and offer an added treatment option for eligible patients.

Response: We thank the applicant and other commenters for their comments regarding the substantial clinical improvement criterion. After consideration of the comments received and the information provided, we agree with the applicant and other commenters that ZEPZELCA™ represents a substantial clinical improvement because it fills an unmet need in second-line treatment for ES–SCLC. Because existing treatments are indicated for patients with platinum-sensitive disease, ZEPZELCA™ treats a disease for which there are no existing treatments. We also believe that, given the context of those patients who were treated, we believe the improvement seen in the matched comparison between topotecan and ZEPZELCA™ in overall survival (25 weeks vs. 11.8 months) and ORR (26% vs. 32%) represents a substantial clinical improvement over existing technologies in the second line treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.

Based on the information received to date and comments received, we have determined that ZEPZELCA™ meets all of the criteria for approval for new technology add-on payments for the reasons stated previously. Therefore, we are approving new technology add-on payments for ZEPZELCA™ for FY 2022. Cases involving the use of ZEPZELCA™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes: XW03387 (Introduction of lurbinectedin into peripheral vein, percutaneous approach, new technology group 7) or XW04387 (Introduction of lurbinectedin into central vein, percutaneous approach, new technology group 7).

In its application, the applicant estimated that the cost of ZEPZELCA™ is $13,266 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of ZEPZELCA™ is $8,622.90 for FY 2022.

6. FY 2022 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, beginning with applications for FY 2021, a medical device that is part of FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation may qualify for the new technology add-on payment under an alternative pathway. Additionally, beginning with FY 2021, a medical product that is designated by the FDA as a Qualified Infectious Disease Product (QIDP) and has received marketing authorization for the indication covered by the QIDP designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still meet the cost criterion.

We note, section 1886(d)(5)(K)(ii)(II) of the Act provides for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. Our regulations in § 412.87(c)(2) for breakthrough devices and § 412.87(d)(2) for certain antimicrobial products state that a medical device/product that meets the condition in paragraph (c)(1) or (d)(1) of § 412.87 will be considered new for not less than 2 years and not more than 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology, the medical technology will no longer be considered ''new'' under the criterion of this section.

We received 17 applications for new technology add-on payments for FY 2022 under the alternative new technology add-on payment pathway. In accordance with the regulations under § 412.87(e)(2), applicants for new technology add-on payments, including Breakthrough Devices, must have FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. We first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold. One applicant withdrew its application prior to the issuance of the proposed rule. Of the remaining 16 applications, 13 of the technologies received a Breakthrough Device designation from FDA and three were designated as a QIDP by FDA. We did not receive any applications for technologies approved through the LPAD pathway. Subsequently, two applicants withdrew their applications for the Neovasc Reducer™ and Thoraflex™ Hybrid Device prior to the issuance of this final rule. Two applicants, BONESUPPORT Inc. (the applicant for CERAMENT® G)

the treatment of recurrent small-cell lung cancer. J Clin Oncol. Vol 17, No 2, 1999: 658–667

[744] Wakuda K, et al. Efficacy of rechallenge chemotherapy in patients with sensitive relapsed small cell lung cancer. Am J Clin Oncol 38(1) (2015) 28–32.

[745] Ibid.

and Phagenesis Ltd. (the applicant for the Phagenyx® System), did not meet the deadline of July 1, 2021 for FDA approval or clearance of the technology and, therefore, the technologies are not eligible for consideration for new technology add-on payments for FY 2022. We note that we did receive some comments requesting that CMS extend the policy that allows for conditional approval for certain antimicrobials to Breakthrough Devices that have not received FDA marketing authorization by July 1 to facilitate timely access to these technologies for beneficiaries. As discussed in the FY 2021 IPPS/LTCH final rule (85 FR 58742), we may consider this for future rulemaking as we gain more experience with this conditional approval process for certain antimicrobial products, but the July 1 deadline for FDA approval or clearance for consideration of new technology add-on payment applications, as set forth in the regulations at § 412.87(e), continues to apply to applications for new technology add-on payments for Breakthrough Devices for FY 2022. A discussion of the remaining 12 applications is presented in this final rule, including 9 technologies that have received a Breakthrough Device designation from FDA and three that were designated as a QIDP by FDA.

Under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742), we revised the regulations at § 412.87(e) by adding a new paragraph (3) which provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for a complete discussion of this policy (85 FR 58737 through 58742).

As we did in the FY 2021 IPPS/LTCH PPS proposed rule, for applications under the alternative new technology add-on payment pathway, in the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to approve or disapprove each of these 12 applications for FY 2022 new technology add-on payments. Therefore, in this section of the preamble of this final rule, we provide background information on each of these 12 alternative pathway applications and discuss whether or not each technology is eligible for the new technology add-on payment for FY 2022. As previously noted, the applications for the Neovasc Reducer™ and Thoraflex™ Hybrid Device were withdrawn prior to the issuance of this final rule, and the remaining two technologies, CERAMENT® G and the Phagenyx® System, did not meet the deadline of July 1, 2021 for FDA approval or clearance of the technology and, therefore, these technologies are not eligible for consideration for new technology add-on payments for FY 2022. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58715 through 58733) for a complete discussion of the alternative new technology add-on payment pathways for these technologies.

a. Alternative Pathway for Breakthrough Devices

(1) Aprevo™ Intervertebral Body Fusion Device

Carlsmed, Inc. submitted an application for new technology-add on payments for the aprevo™ Intervertebral Fusion Device (aprevo™) for FY 2022. Per the applicant, the device is an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures indicated for the treatment of spinal deformity. The applicant states that the implant device is custom made for patient-specific features, by using patient CT scans to create 3D virtual models of the deformity. The device is used during anterior lumbar interbody fusion, lateral lumbar interbody fusion, transforaminal lumbar interbody fusion, or standalone anterior lumbar interbody fusion procedures. According to the applicant, the aprevo™ device is additively manufactured and made from Titanium Alloy (Ti-6Al-4V) per ASTM F3001, and has a cavity intended for the packing of bone graft. In addition, the applicant explained that aprevo™ is used with supplemental fixation devices and bone graft packing. Per the applicant, the device was formerly known as ''Corra™.''

The aprevo™ device received FDA Breakthrough Device designation under the name ''Corra'' on July 1, 2020 for the Corra Anterior, Corra Transforaminal and Corra Lateral Lumbar Fusion System interbody device which is intended for use in anterior lumbar interbody fusion (ALIF), lateral lumbar interbody fusion (LLIF), and transforaminal lumbar interbody fusion (TLIF) under this designation. The applicant was granted FDA 510(k) clearance as a Class II medical device for the anterior lumbar interbody fusion and lateral lumbar interbody fusion indications on December 3, 2020. We stated in the proposed rule that the applicant anticipated that the aprevo™ device would receive FDA marketing authorization by May 2021 for the additional indications of transforaminal interbody fusion and standalone anterior lumbar interbody fusion (which incorporates supplemental fixation), and was granted 510(k) clearance for the TLIF indication on June 30, 2021. Since the anterior and lateral lumbar fusion indications that received marketing authorization on December 3, 2020 correspond to the indications that received Breakthrough Device designation, we stated that we believed the newness date for these indications would be December 3, 2020. The transforaminal interbody fusion indication, which also corresponds to the indication that received Breakthrough Device designation, received marketing authorization on June 30, 2021, and we therefore believe the newness date for this indication would be June 30, 2021. We noted that under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of aprevo™ for the ALIF, LLIF, and TLIF indications, and the FDA Breakthrough Device designations it received for these uses, are relevant for purposes of the new technology add-on payment application for FY 2022. As the use of aprevo™ for the standalone indication is not included in the Breakthrough Device designation indications, it is not eligible for new technology add-on payments.

The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a code for FY 2022 to uniquely identify the technology and was granted approval for the following procedure codes effective October 1, 2021:

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XRGA0R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, open approach, new technology group 7
XRGA3R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGA4R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGB0R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, open approach, new technology group 7
XRGB3R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGB4R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGC0R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, open approach, new technology group 7
XRGC3R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGC4R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGD0R7	Fusion of lumbosacral joint using customizable interbody fusion device, open approach, new technology group 7
XRGD3R7	Fusion of lumbosacral joint using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGD4R7	Fusion of Lumbosacral Joint using Customizable Interbody Fusion Device, Percutaneous Endoscopic Approach, New Technology Group 7

With respect to the cost criterion, the applicant provided the following analysis. The applicant used the MS–DRG grouping function within FindACode software in conjunction with the online MS–DRG v37.0 Definitions Manual to identify the appropriate MS–DRGs to which potential cases that may be eligible for treatment involving aprevo™ patient-specific interbody cages would most likely map. The applicant identified the following six relevant MS–DRGs:

MS-DRG	DESCRIPTOR
453	Combined Anterior/Posterior Spinal Fusion With Mcc
454	Combined Anterior/Posterior Spinal Fusion With Cc
455	Combined Anterior/Posterior Spinal Fusion Without Cc/Mcc
456	Spinal Fusion Except Cervical With Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions With Mcc
457	Spinal Fusion Except Cervical With Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions With Cc
458	Spinal Fusion Except Cervical With Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions Without Cc/Mcc

The applicant conducted a review of ICD–10–PCS codes for procedures in which the aprevo™ patient-specific intervertebral body fusion cases might be placed into the lumbar spine of an adult patient diagnosed with spinal curvature. For MS–DRGs 453, 454, and 455, the applicant searched the FY 2019 MedPAR dataset for cases with any of the following procedure codes:

ICD-10-PCS Codes	DESCRIPTOR
0SG00A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG00AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG03A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG03AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG04A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG04AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG10A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, open approach
0SG10AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, open approach
0SG13A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG13AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG14A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG14AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG30A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG30AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG33A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG33AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG34A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG34AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach

For MS–DRGs 456, 457, and 458, the applicant searched the FY 2019 MedPAR dataset for cases reporting a procedure code in Table A in combination with a primary diagnosis code in Table B or a secondary diagnosis code in Table C.

Table A – Procedure Codes	
0RGA3A0	Fusion of thoracolumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0RGA3AJ	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0RGA4A0	Fusion of thoracolumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0RGA4AJ	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG00A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG00AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG03A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG03AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG04A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG04AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG10A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, open approach
0SG10AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, open approach
0SG13A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG13AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG14A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG14AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG30A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG30AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG33A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG33AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG34A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG34AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach

Table B – Primary Diagnosis Codes	
M4000	Postural kyphosis, site unspecified
M4004	Postural kyphosis, thoracic region
M4005	Postural kyphosis, thoracolumbar region
M4010	Other secondary kyphosis, site unspecified
M4014	Other secondary kyphosis, thoracic region
M4015	Other secondary kyphosis, thoracolumbar region
M40204	Unspecified kyphosis, thoracic region
M40205	Unspecified kyphosis, thoracolumbar region
M40209	Unspecified kyphosis, site unspecified
M40294	Other kyphosis, thoracic region
M40295	Other kyphosis, thoracolumbar region
M40299	Other kyphosis, site unspecified
M4030	Flatback syndrome, site unspecified
M4035	Flatback syndrome, thoracolumbar region
M4036	Flatback syndrome, lumbar region
M4037	Flatback syndrome, lumbosacral region
M4040	Postural lordosis, site unspecified
M4045	Postural lordosis, thoracolumbar region
M4046	Postural lordosis, lumbar region
M4047	Postural lordosis, lumbosacral region
M4050	Lordosis, unspecified, site unspecified
M4055	Lordosis, unspecified, thoracolumbar region
M4056	Lordosis, unspecified, lumbar region
M4057	Lordosis, unspecified, lumbosacral region
M4120	Other idiopathic scoliosis, site unspecified
M4124	Other idiopathic scoliosis, thoracic region
M4125	Other idiopathic scoliosis, thoracolumbar region
M4126	Other idiopathic scoliosis, lumbar region
M4127	Other idiopathic scoliosis, lumbosacral region
M4130	Thoracogenic scoliosis, site unspecified
M4134	Thoracogenic scoliosis, thoracic region
M4135	Thoracogenic scoliosis, thoracolumbar region
M4140	Neuromuscular scoliosis, site unspecified

Table B – Primary Diagnosis Codes	
M4144	Neuromuscular scoliosis, thoracic region
M4145	Neuromuscular scoliosis, thoracolumbar region
M4146	Neuromuscular scoliosis, lumbar region
M4147	Neuromuscular scoliosis, lumbosacral region
M4150	Other secondary scoliosis, site unspecified
M4154	Other secondary scoliosis, thoracic region
M4155	Other secondary scoliosis, thoracolumbar region
M4156	Other secondary scoliosis, lumbar region
M4157	Other secondary scoliosis, lumbosacral region
M4180	Other forms of scoliosis, site unspecified
M4184	Other forms of scoliosis, thoracic region
M4185	Other forms of scoliosis, thoracolumbar region
M4186	Other forms of scoliosis, lumbar region
M4187	Other forms of scoliosis, lumbosacral region
M419	Scoliosis, unspecified
M438X4	Other specified deforming dorsopathies, thoracic region
M438X5	Other specified deforming dorsopathies, thoracolumbar region
M438X6	Other specified deforming dorsopathies, lumbar region
M438X7	Other specified deforming dorsopathies, lumbosacral region
M438X8	Other specified deforming dorsopathies, sacral and sacrococcygeal region
M438X9	Other specified deforming dorsopathies, site unspecified
M439	Deforming dorsopathy, unspecified
M4850XA	Collapsed vertebra, not elsewhere classified, site unspecified, initial encounter for fracture
M4854XA	Collapsed vertebra, not elsewhere classified, thoracic region, initial encounter for fracture
M4855XA	Collapsed vertebra, not elsewhere classified, thoracolumbar region, initial encounter for fracture
M4856XA	Collapsed vertebra, not elsewhere classified, lumbar region, initial encounter for fracture
M4857XA	Collapsed vertebra, not elsewhere classified, lumbosacral region, initial encounter for fracture
M4858XA	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, initial encounter for fracture
M8008XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M8088XA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M8458XA	Pathological fracture in neoplastic disease, other specified site, initial encounter for fracture
M8468XA	Pathological fracture in other disease, other site, initial encounter for fracture
M962	Postradiation kyphosis
M963	Postlaminectomy kyphosis
M964	Postsurgical lordosis
M965	Postradiation scoliosis
Q675	Congenital deformity of spine
Q763	Congenital scoliosis due to congenital bony malformation
Q76425	Congenital lordosis, thoracolumbar region
Q76426	Congenital lordosis, lumbar region
Q76427	Congenital lordosis, lumbosacral region
Q76428	Congenital lordosis, sacral and sacrococcygeal region
Q76429	Congenital lordosis, unspecified region

Table C – Secondary Diagnosis Codes	
M4010	Other secondary kyphosis, site unspecified
M4014	Other secondary kyphosis, thoracic region
M4015	Other secondary kyphosis, thoracolumbar region
M4140	Neuromuscular scoliosis, site unspecified
M4144	Neuromuscular scoliosis, thoracic region
M4145	Neuromuscular scoliosis, thoracolumbar region
M4146	Neuromuscular scoliosis, lumbar region
M4147	Neuromuscular scoliosis, lumbosacral region
M4150	Other secondary scoliosis, site unspecified
M4154	Other secondary scoliosis, thoracic region
M4155	Other secondary scoliosis, thoracolumbar region
M4156	Other secondary scoliosis, lumbar region
M4157	Other secondary scoliosis, lumbosacral region
M438X9	Other specified deforming dorsopathies, site unspecified

BILLING CODE 4120–01–C

The applicant identified 45,331 cases across all six MS–DRGs. The applicant first removed charges to account for the two types of prior technology devices that the applicant asserted are most likely to be replaced by aprevo™ Intervertebral Body Fusion Device. Specifically, the applicant calculated an average cost for the top five selling devices in each category of prior technology, which include standalone ALIF and LLIF lateral expandable cages.[746] The applicant then multiplied the cost of the technology being replaced by three, which, per the applicant, is the number of lumbar cages implanted for the correction of spinal curvature, to arrive at an estimated hospital cost per case.[747] The applicant converted costs to charges by weighting the operating cost-to-charge ratios for each of the 3,315 hospitals in the FY 2021 IPPS/LTCH final rule and correction notice impact file by each hospital's share of the 9,235,824 submitted claims to obtain a national average CCR of 0.2546, of which the inverse is a national-average hospital markup of 393 percent. The applicant then standardized the charges and applied an inflation factor of 13.1 percent, which, per the applicant, is the outlier charge inflation factor used in the FY 2021 IPPS/LTCH final rule (85 FR 59038), to update the charges from FY 2019 to FY 2021. We note that the applicant appears to have used the FY 2021 IPPS/LTCH PPS proposed rule inflation factor rather than the 2-year inflation factor from the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent (85 FR 59039), which would have resulted in a higher inflated charge figure. The applicant then added charges for the new technology by multiplying the estimated average cost for the aprevo™ Intervertebral Body Fusion Device by three devices per case and converting the cost to charges using the 393 percent hospital charge markup.

The applicant calculated a final inflated case-weighted average standardized charge per case of $247,648 and an average case-weighted threshold of $157,600. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25364), we agreed with the applicant that the aprevo™ Intervertebral Body Fusion meets the cost criterion and therefore proposed to approve the aprevo™ Intervertebral Body Fusion device for the indications of ALIF and LLIF, and for the indication of TLIF, subject to the technology receiving FDA marketing authorization for that indication by July 1, 2021, as these indications correspond to the Breakthrough Device designation, for new technology add-on payments for FY 2022.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of the aprevo™ Intervertebral Body Fusion is $31,500, or an estimated average cost of $10,500 per device multiplied by three, which, according to the applicant, is the average number of devices used per procedure. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the aprevo™ Intervertebral Body Fusion Device would be $20,475 for FY 2022 (that is 65 percent of the average cost of the technology).

We invited public comments on whether the aprevo™ Intervertebral Body Fusion Device meets the cost criterion and our proposal to approve new technology add-on payments for aprevo™ Intervertebral Body Fusion Device for FY 2022 for ALIF and LLIF, and for TLIF, subject to the technology receiving marketing authorization for that indication by July 1, 2021.

Comment: We received several comments expressing support for the approval of the aprevo™ Intervertebral Body Fusion Device for the new technology add-on payment for FY 2022. The commenters stated that aprevo™ provides a more effective treatment for surgeries for adult spinal deformities and improves patient care by reducing complications. Also, a commenter expressed general support for the approval of the aprevo™ Intervertebral Body Fusion Device as an orthopaedic device which advances the care of musculoskeletal disorders and improves patients' quality of life.

Response: We appreciate the commenters' support.

Comment: The applicant submitted a comment noting that CMS determines eligibility for the new technology add-on payment based on the newness of the technology, which has been established in regulation as being measured from the first date upon which data become available reflecting inpatient use of the technology. The applicant requested that CMS adjust the beginning of the newness period for the aprevo™ Intervertebral Body Fusion Device from the date of FDA clearance on December 3, 2020, to the date the device was first used commercially on February 23, 2021. Per the applicant, using the date of FDA approval or clearance as the basis for the start of the newness period does not account for situations where a product may be approved by the FDA for distribution and use but is not yet being distributed to or used by hospitals in caring for patients.

Response: We thank the applicant for its comment. As we have discussed in prior rulemaking (77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant states that the aprevo™ Intervertebral Body Fusion Device was first used commercially on February 23, 2021, but it is unclear from the information provided when the technology first became available for sale and, absent additional information from the applicant, we cannot determine a newness date based on a documented delay in the technology's availability on the U.S. market. However, we note that using either the FDA clearance date of December 3, 2020, or the date suggested by manufacturer of February 23, 2021, aprevo™ is still considered new for FY 2022 because the 3-year anniversary date (December 3, 2023 or February 23, 2024, respectively) would occur after FY 2022.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the aprevo™ Intervertebral Body Fusion meets the cost criterion. The aprevo™ Intervertebral Body Fusion received marketing authorization from the FDA on December 3, 2020 for the indications for ALIF and LLIF and on June 30, 2021 for the indication for TLIF, that are covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the aprevo™ Intervertebral Body Fusion for FY 2022, and we consider the beginning of the newness period to commence on December 3, 2020 for the indications for ALIF and LLIF and June 30, 2021 for the indication for TLIF, which is when the technology received FDA marketing authorization for the indications

[746] Orthopedic Network News. ''2019 Spinal Surgery update.'' Volume 30, No. 4. October 2019.

[747] Ibid.

covered by its Breakthrough Device designation. Based on the information at the time of this final rule, the cost per case is $31,500 or an estimated average cost of $10,500 per device multiplied by three, which, according to the applicant, is the average number of devices used per procedure. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the aprevo™ Intervertebral Body Fusion Device would be $20,475 for FY 2022 (that is 65 percent of the average cost of the technology). Cases involving the use of the aprevo™ Intervertebral Body Fusion Device that are eligible for new technology add-on payments will be identified by any of the following ICD–10–PCS codes:

XRGA0R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, open approach, new technology group 7
XRGA3R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGA4R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGB0R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, open approach, new technology group 7
XRGB3R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGB4R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGC0R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, open approach, new technology group 7
XRGC3R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGC4R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGD0R7	Fusion of lumbosacral joint using customizable interbody fusion device, open approach, new technology group 7
XRGD3R7	Fusion of lumbosacral joint using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGD4R7	Fusion of lumbosacral joint using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7

(2) aScope™ Duodeno

Ambu, Inc. submitted an application for new technology add on payments for the aScope™ Duodeno for FY 2022. The device is a sterile, single-use endoscope for endoscopy and endoscopic surgery indicated for treatment of the upper gastrointestinal (GI) tract. Per the applicant, the device includes a flexible insertion tube with a bendable tip equipped with lighting and camera. According to the applicant, the aScope™ Duodeno is inserted into the mouth of the patient and steered via the esophagus and stomach to the duodenum. The applicant states that single-use scopes eliminate the risk of patient-to-patient transmission of infection related to reprocessing. The applicant also states the device is designed to be used with aBox Duodeno, which is a video processor that outputs video imaging for observation and recording. Per the applicant, the device may also be used with existing external video monitors for image display as well as other endoscopic accessories and equipment.

The aScope™ Duodeno (formerly aScope 1 Duo) was designated as a Breakthrough Device, indicated for use with the aScope Base (now aBox Duodeno), endo-therapy accessories (for example, biopsy forceps) and other ancillary equipment (for example, video monitor) for endoscopy and endoscopic surgery within the duodenum, and received FDA 510(k) clearance as a Class II medical device on July 17, 2020 for the same indication. Per the applicant, the device was available on the market immediately after FDA clearance.

The applicant stated that the applicant for EXALT™ Model D, another technology discussed in this section, submitted a request to the ICD–10 Coordination and Maintenance Committee for FY 2022 for a unique code to identify use of single-use duodenoscopes. The applicant further stated that since this code would describe and identify use of aScope, they did not submit a request for approval of a code to uniquely identify the technology. The applicant for aScope™ Duodeno was granted approval for the following procedure codes effective October 1, 2021: XFJB8A7 (Inspection of hepatobiliary duct using single-use duodenoscope, new technology group 7) and XFJD8A7 (Inspection of pancreatic duct using single-use duodenoscope, new technology group 7).

To demonstrate that the technology meets the cost criterion, the applicant searched the FY 2019 MedPAR Limited Data Set (LDS) for cases reporting one of the following ICD–10–PCS codes commonly used to report endoscopic retrograde cholangiopancreatography (ERCP) and use of duodenoscopes:

BILLING CODE 4120–01–P

0FD48ZX	Extraction of gallbladder, via natural or artificial opening endoscopic, diagnostic
0FD58ZX	Extraction of right hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FD68ZX	Extraction of left hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FD78ZX	Extraction of common hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FD88ZX	Extraction of cystic duct, via natural or artificial opening endoscopic, diagnostic
0FD98ZX	Extraction of common bile duct, via natural or artificial opening endoscopic, diagnostic
0FDC8ZX	Extraction of ampulla of vater, via natural or artificial opening endoscopic, diagnostic
0FDD8ZX	Extraction of pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FDF8ZX	Extraction of accessory pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FJ48ZZ	Inspection of gallbladder, via natural or artificial opening endoscopic
0FJB8ZZ	Inspection of hepatobiliary duct, via natural or artificial opening endoscopic
0FJD8ZZ	Inspection of pancreatic duct, via natural or artificial opening endoscopic
0FB48ZX	Excision of gallbladder, via natural or artificial opening endoscopic, diagnostic
0FB58ZX	Excision of right hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FB68ZX	Excision of left hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FB78ZX	Excision of common hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FB88ZX	Excision of cystic duct, via natural or artificial opening endoscopic, diagnostic
0FB98ZX	Excision of common bile duct, via natural or artificial opening endoscopic, diagnostic
0FBC8ZX	Excision of ampulla of vater, via natural or artificial opening endoscopic, diagnostic
0FBD8ZX	Excision of pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FBF8ZX	Excision of accessory pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FN98ZZ	Release common bile duct, via natural or artificial opening endoscopic
0FNC8ZZ	Release ampulla of vater, via natural or artificial opening endoscopic
0FND8ZZ	Release pancreatic duct, via natural or artificial opening endoscopic
0FNF8ZZ	Release accessory pancreatic duct, via natural or artificial opening endoscopic
4A0C8BZ	Measurement of biliary pressure, via natural or artificial opening endoscopic
0FF78ZZ	Fragmentation in common hepatic duct, via natural or artificial opening endoscopic
0FF98ZZ	Fragmentation in common bile duct, via natural or artificial opening endoscopic

BILLING CODE 4120–01–C

The applicant excluded MS–DRGs that had fewer than 100 cases from the analysis. The applicant did not say how many cases it excluded based on this criterion.

In total, the applicant identified 54,848 cases across 40 unique MS–DRGs. The applicant then removed charges for prior technology by dividing the per use cost for reusable duodenoscopes and related components [748] by the hospital-specific cost-to-charge ratio from the FY 2021 IPPS/LTCH Proposed Rule Impact File at the claims level and averaging the resulting estimated charges by MS–DRG. The applicant then standardized the charges and applied an inflation factor of 13.2 percent, or the 2-year inflation factor used to update the outlier threshold in the FY 2021 IPPS/LTCH final rule (85 FR 59039), to update the charges from FY 2019 to FY 2021. The applicant added charges for the aScope™ Duodeno and related components by dividing the cost per use by the national cost-to-charge ratio of 0.2970 for Supplies and Equipment (85 FR 58601).

[748] Derived from Travis, et al. minus the 20 percent overhead cost.

The applicant calculated a final inflated average case-weighted standardized charge per case of $89,945 and an average case-weighted threshold of $64,894. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25366), we agreed with the applicant that the aScope™ Duodeno meets the cost criterion; and therefore, we proposed to approve the aScope™ Duodeno for new technology add-on payments for FY 2022.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of the aScope™ Duodeno is $2,184.27. However, the applicant noted in its application that this cost is broken down into three components, including the disposable sleeve, the aBox Duodeno (a video processor and light source), and other endoscopic accessories and equipment. We stated that we believed it is appropriate to only consider the cost of the disposable sleeve as the cost of the technology, as the other two components, which include the aBox Duodeno and an external monitor that, per the applicant, do not incur new costs per use, would thus be paid for under the IPPS for capital-related costs. As noted previously, because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add on payments under the IPPS for capital-related costs. Thus, we stated that we believe the operating cost of the aScope™ Duodeno is $1,995.

Based on the information available at the time of the proposed rule, we stated that it appeared that both aScope™ Duodeno and EXALT™ Model D will be identified by the same ICD–10–PCS code and share the same indication for endoscopy and endoscopic surgery within the duodenum. We stated that as we are unable to separately identify these cases to apply two separate payment amounts for these technologies, we were proposing to use a case-weighted average to calculate a single cost that would be used to

determine the new technology add-on payment amount for both technologies. To compute the weighted average cost, we summed the total number of projected cases for each of the applicants, which equaled 12,064 (3,750 plus 8,314). Then we divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 31 percent for aScope™ Duodeno and 69 percent for EXALT™ Model D. We multiplied the cost per case for the manufacturer specific technology by the case-weighted percentage (0.31 * $1,995 = $620.13 for aScope™ Duodeno and 0.69 * $2,930 = $2,019.23 for EXALT™ Model D). This resulted in a case-weighted average cost of $2,639.36 for both technologies. We invited public comments on the proposed case-weighted average, as well as any alternative approaches for determining and applying the new technology add-on payment amount for cases involving these technologies, for FY 2022.

We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of aScope™ Duodeno or EXALT™ Model D would be $1,715.59 for FY 2022 (that is, 65 percent of the case-weighted average cost of both technologies).

We invited public comments on whether aScope™ Duodeno meets the cost criterion and our proposal to approve new technology add-on payments for aScope™ Duodeno for FY 2022. We further invited public comments on the calculation of the maximum new technology add-on payment amount for the aScope™ Duodeno.

We did not receive comments on our proposals for the aScope™ Duodeno for the new technology add-on payment for FY 2022. As we discuss later in this section, we separately received comments from the applicant for the EXALT™ Model D supporting CMS' proposal to use a case-weighted average to calculate a single cost that would be used to determine the new technology add-on payment amount.

Based on the information provided in the application for new technology add-on payments we believe aScope™ Duodeno meets the cost criterion. Also, aScope™ Duodeno received marketing authorization from the FDA on July 17, 2020 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for aScope™ Duodeno for FY 2022, and we consider the beginning of the newness period to commence on July 17, 2020 which is when the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation. Based on the information at the time of this final rule, and using the case-weighted average cost as described in the proposed rule and earlier in this final rule, the cost per case is $2,639.36. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the aScope™ Duodeno or EXALT™ Model D would be $ 1,715.59 for FY 2022 (that is 65 percent of the case-weighted average cost of both technologies). Cases involving the use of the aScope™ Duodeno eligible for new technology add-on payments will be identified by ICD–10– PCS codes: XFJB8A7 (Inspection of hepatobiliary duct using single-use duodenoscope, new technology group 7) or XFJD8A7 (Inspection of pancreatic duct using single-use duodenoscope, new technology group).

(3) Caption Guidance™

Caption Health, Inc. submitted an application for new technology-add on payments for Caption Guidance™ for FY 2022. Per the applicant, Caption Guidance™ is an artificial intelligence (AI) guided medical imaging acquisition software system indicated for the acquisition of cardiac ultrasound images. The applicant explained that the system provides real-time guidance during transthoracic echocardiography (2D–TTE) to assist in obtaining anatomically correct and optimized images that represent standard 2D echocardiographic diagnostic views and orientations. The applicant also states that the technology is classified by FDA as software as a medical device (SaMD), so in order to use the software, the Caption Guidance™ system must be installed on a compatible third-party ultrasound system.

Caption Guidance™ is designated as a Breakthrough Device, indicated to assist medical professionals in the acquisition of cardiac ultrasound images, and received FDA De Novo approval on February 7, 2020 for the same indication. The applicant stated that an updated version of the system subsequently received 510(k) clearance under 510(k) number K200755 on April 16, 2020 on an expedited basis due to COVID–19. Per the applicant, an interim version of the software became available on March 17, 2020, though not sold, on an emergency basis to assist sites in responding to the COVID–19 pandemic. According to the applicant, the first version of the technology was released commercially on September 15, 2020 with a first date of sale of September 29, 2020. Therefore, we stated that we believe that the newness date for this technology is the date on which Caption Guidance™ became available on the market, September 15, 2020. The item is a Class II medical device assigned to product code QJU with descriptor Image Acquisition And/Or Optimization Guided By Artificial Intelligence. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for a new code to uniquely identify the technology and was granted approval to identify Caption Guidance™ using the following procedure code effective October 1, 2021: X2JAX47 (Inspection of heart using transthoracic echocardiography, computer-aided guidance, new technology group 7).

Comment: Several commenters, including the applicant, supported the proposal to consider September 15, 2020, as the date on which Caption Guidance™ became available for purposes of evaluating the newness period for new technology add-on payments. The applicant stated that the proposed newness date is appropriate given that, during FY 2019, which is the time period of the data CMS proposed to use for recalibrating the MS–DRGs, Caption Guidance was not yet commercially available and as a result, the claims do not adequately reflect the cost of technology. In addition, the applicant stated that CMS has defaulted to the FDA approval date despite other reasons being provided by applicants regarding the date of first commercial availability. Another commenter also stated that requiring a manufacturer to submit information rebutting a presumption that the date of first availability is the date of FDA marketing authorization adds unnecessary burden and complexity to the new technology add-on payments application and review process. The commenter believes that a more efficient and appropriate policy would be for the new technology add-on payment newness period to

begin with the date of the first claim, which is consistent with the definition of newness used in determining the period of eligibility for Transitional Pass-through status in the Hospital Outpatient Prospective Payment System (OPPS).

Response: We thank the commenters for their support and feedback and agree that the newness date for this technology is the date on which Caption Guidance™ became available on the market, September 15, 2020, and that Caption Guidance™ meets the newness criterion for FY 2022. We note that though, generally, our policy is to begin the newness period on the date of FDA approval or clearance, we may consider a documented delay in the technology's market availability in our determination of newness (77 FR 53348 and 70 FR 47341).

Regarding the commenter's belief that beginning the newness period on the date of first claim would be a more efficient and appropriate policy, as well as consistent with the definition of newness used in determining the period of eligibility for Transitional Pass-through status in OPPS, we note that ''newness'' for purposes of the OPPS pass-through policy refers to a drug, biological, or device's eligibility for pass-through status. In particular, for pass-through drugs and biologicals, ''newness'' means that the drug or biological was first payable as an outpatient hospital service after December 31, 1996. For pass-through devices, ''newness'' means that CMS received the applicant's pass-through application within 3 years of the date of FDA approval for the device. It appears the commenter is referring not to newness in terms of eligibility for OPPS pass-through status, but rather to the two-to-three-year period for pass-through status can be in effect. Under §§ 419.64(c)(2) and 419.66(g), the pass-through period begins on the date on which CMS makes its first pass-through payment for a drug, biological, or device. For new technology add-on payments, as we have discussed in prior rulemaking (77 FR 53348) and noted above, generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market.

With respect to the cost criterion, the applicant searched the CY 2019 Limited Data Set (LDS)—Carrier Standard Analytic File (SAF), 5 percent sample, for beneficiaries receiving limited echocardiography, as described by Current Procedural Terminology (CPT®) code 93308 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study) with a place of service code 21 (inpatient hospital) or 23 (emergency department) and the associated inpatient stays. Per the applicant, limited echocardiography, the procedure most likely to include Caption Guidance, is not reliably reported in the inpatient setting. As a result, the applicant used a multi-step approach where corresponding inpatient stays were identified in the CY 2019 LDS—Inpatient SAF for the beneficiaries identified in the Carrier SAF. Inpatient stays were identified by matching on the unique beneficiary ID and by matching the carrier claim date of service against the inpatient admission and discharge dates. The applicant counted an inpatient stay if the date of service for CPT code 93308 occurred on or after the inpatient admission date (or during the three days preceding the date of admission), but was also on or before the discharge date of the hospital stay. The applicant eliminated non-inpatient claims and claims with a payment amount less than or equal to zero, as well as claims from hospitals that are not used in the ratesetting process.

The applicant summarized the remaining claims by MS–DRG, and by principal diagnosis and MS–DRG. The applicant cross-walked the MS–DRG codes to FY 2021 MS–DRG definitions using the MS–DRG grouper for FY 2021 and identified a list of 461 unique MS–DRGs to which cases representing patients who may be eligible for use of Caption Guidance™ mapped. The applicant also utilized data from current Caption Guidance™ customers to obtain a list of principal diagnoses associated with each MS–DRG. The applicant noted that, because this analysis began with the CY 2019 LDS Carrier SAF, 5 percent sample, the inpatient claims captured underrepresent the total number of inpatient stays in which CPT code 93308 is expected to be performed. The applicant applied the unique MS–DRG and principal diagnosis combinations to all inpatient claims in the CY 2018 and CY 2019 LDS SAF with a discharge date in FY 2019. The applicant then removed any claims where there were no billed charges in revenue centers 0480 (Cardiology-General) and 0483 (Cardiology-Echocardiology). The applicant explained that MS–DRG and principal diagnosis alone are unlikely to be a good proxy for performance of CPT code 93308. The applicant noted that there are charges to revenue centers 0480 and 0483 among nearly 100 percent of cases identified, and that no other revenue centers were billed at such high frequency. The applicant explained that it did not use the FY 2021 MedPAR LDS for this reason, as the dataset does not report charges by revenue center.

The applicant identified 1,932,386 cases mapping to 461 MS–DRGs. Then the applicant standardized the charges and applied the 2-year charge inflation factor used to adjust the outlier threshold determination, which the applicant stated was 10.22 percent. We note that the applicant appears to have used an inflation factor lower than the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent (85 FR 59039), which would have resulted in a higher inflated charge figure. The applicant did not remove charges for prior technology as the applicant maintained that no existing technology is comparable to Caption Guidance™.

The applicant then added charges for the new technology. The applicant calculated the technology's cost per case in a multi-step process. First, the applicant multiplied the cost of Caption Guidance™ by the number of devices under the CCN of each subscribing provider to obtain a provider-specific total device cost. Next, for each subscribing provider, the applicant identified Medicare inpatient cases that would be eligible for Caption Guidance™ using the criteria and methodology described previously. The applicant then multiplied the number of inpatient cases by 15 percent, which per the applicant is consistent with published evidence that the percent of limited echocardiography cases ranged from 12 to 15 percent of all inpatient echocardiography services.[749] The applicant then added the number of Medicare hospital outpatient cases for CPT code 93308 for each subscribing provider to the estimated inpatient limited echocardiography utilization to estimate total Medicare limited echocardiography by provider. The applicant divided the total Medicare inpatient and outpatient cases receiving limited echocardiogram by an average Medicare share of 63 percent, which the applicant estimated by analyzing discharges reporting three ICD–10–PCS codes: B244ZZZ (Ultrasonography of right heart), B245ZZZ (Ultrasonography of left heart), and B246ZZZ (Ultrasonography of right and left heart) from HCUPnet's Nationwide Inpatient

[749] Ward RP, Lee L, Ward TJ, Lang RM. Utilization and Appropriateness of Transthoracic Echocardiography in Response to he COVID–19 Pandemic. *J Am Soc Echoardiogr.* 2020 June;33(6):690–691. doi: 101.1016/j.echo.2020.04.006. Epub 2020 April 10.

Sample, 2017, to obtain the total limited echocardiography cases. The applicant then divided the total device cost by the total limited echocardiography cases to obtain a provider-specific cost per case, which it then averaged across all subscriber hospitals. Finally, the applicant converted the cost per case to charges per case by dividing the cost per case by the national average cost-to-charge ratio for the cardiology cost center of 0.094 (85 FR 58601).

The applicant calculated a final inflated case-weighted average standardized charge per case of $113,435 and an average case-weighted threshold of $69,197. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agreed with the applicant that, using the cost per case provided by the applicant, the Caption Guidance™ system would meet the cost criterion and therefore proposed to approve the Caption Guidance™ system for new technology add-on payments for FY 2022.

We stated that based on preliminary information from the applicant at the time of proposed rule, the cost per case of the Caption Guidance™ system is $2,874. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the Caption Guidance™ system would be $1,868.10 for FY 2022 (that is 65 percent of the average cost of the technology).

In the proposed rule, we stated our concern that the applicant appears to have used a single list price of Caption Guidance™ per hospital with a cost per patient that can vary based on the volume of cases. We stated that we were interested in information about whether the cost per patient varies based on the utilization of the technology by the hospitals. We stated that the cost per patient could be skewed by the small number of hospitals utilizing the technology and their low case volumes. It is possible, if hospitals with large patient populations adopt Caption Guidance™, the cost per patient would be significantly lower.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58628), in a similar instance, we stated our understanding that there are unique circumstances to determining a cost per case for a technology that utilizes a subscription for its cost. We invited comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

We invited public comments on whether the Caption Guidance™ system meets the cost criterion and our proposal to approve new technology add-on payments for Caption Guidance™ system for FY 2022, including on whether the newness period for this technology would begin on September 15, 2020.

Comment: We received a few comments on our request for comment regarding technologies sold on a subscription basis and whether the cost per case should be estimated based on subscriber hospital data, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment. Most commenters agreed that in determining the cost per case for technologies seeking new technology add-on payment that utilize a subscription model, we should limit our analysis to subscriber hospitals and update the cost analysis on an annual basis. A commenter noted that alternative methodologies involving estimating the number of patients who would be eligible to receive treatment utilizing a technology sold on a subscription basis would be likely to result in a payment amount that does not adequately reflect the estimated average cost of such service or technology as required by the statute. The commenter believes that given the direct impact of utilization changes on cost per case when using a subscription model, it is reasonable for CMS to annually update the payment amount using the most recent subscriber utilization data.

We also received a comment from the applicant stating that Caption Guidance™ had been commercially available for less than 30 days prior to the application deadline and that the first sale was completed within two weeks of this deadline. The applicant stated as there were too few subscriber hospitals to limit the cost per case analysis to just subscribers, they calculated the anticipated cost per case across all IPPS hospitals. The applicant explained that each hospital's anticipated total cost was determined based on the estimated number of devices multiplied by the list price per device. The applicant then explained that the cost per case was calculated using the anticipated total device costs and the estimated number of Medicare and non-Medicare cases. The applicant stated that an average of these unique costs per case was taken to derive the average cost per case across all IPPS hospitals, which the applicant then converted to charges using the national average cost-to-charge ratio of 0.094 for cardiology cost centers (85 FR 58601). The applicant also noted that it updated its cost analysis with the correct inflation factor of 13.22 percent as advised in the FY 2022 IPPS proposed rule and stated that with the change, the technology still meets the cost criterion.

Response: We thank the commenters for the support and feedback and agree that Caption Guidance™ meets the cost criterion. We also thank the commenters for their feedback on determining a cost per case for technologies sold on a subscription basis. CMS will continue to consider the issues relating to calculation of the cost per unit of technologies sold on a subscription basis, including the merits of calculating the cost per case across all IPPS hospitals versus limiting the cost per case analysis to current users and whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment, as we gain more experience in this area.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe Caption Guidance™ system meets the cost criterion. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Caption Guidance™ system for FY 2022, and we consider the beginning of the newness period to commence on September 15, 2020 which is when the technology became commercially available for the indication covered by its Breakthrough Device designation. Based on the information at the time of this final rule, the cost per case of the Caption Guidance™ system is $2,874. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS DRG payment

for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Caption Guidance™ system would be $1,868.10 for FY 2022 (that is 65 percent of the average cost of the technology). Cases involving the use of the Caption Guidance™ system that are eligible for new technology add-on payments will be identified by ICD–10–PCS code: X2JAX47 (Inspection of heart using transthoracic echocardiography, computer-aided guidance, new technology group 7).

(5) EXALT™ Model D Single-Use Duodenoscope

Boston Scientific Corporation applied for new technology-add on payments for EXALT™ Model D Single-Use Duodenoscope (EXALT™) for FY 2022. Per the applicant, EXALT™ is a single-use, flexible duodenoscope indicated for diagnostic and therapeutic treatment of the pancreaticobiliary system during endoscopic retrograde cholangiopancreatography (ERCP) procedures. According to the applicant, the scope is most commonly used to facilitate therapeutic maneuvers such as removal of gallstones from the bile ducts, dilation of strictures in the bile or pancreatic ducts, or to relieve an obstruction by inserting a plastic or metal stent. The applicant states that EXALT™ is intended to eliminate the risk of patient-to-patient transmission of infection related to reprocessing of reusable duodenoscopes.

EXALT™ is designated as a Breakthrough Device, indicated for intended use with a Boston Scientific endoscopic video imaging system for endoscopy and endoscopic surgery within the duodenum, and received FDA 510(k) clearance as a Class II medical device on December 13, 2019 for the same indication. The applicant indicates that this device is the first FDA-cleared single-use duodenoscope in the U.S. According to the applicant, EXALT™ was available on the market immediately after FDA approval. The applicant listed 50 ICD–10–PCS codes that describe ERCP and other procedures in which EXALT™ and other duodenoscopes are used. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a code to uniquely identify the technology and was granted approval to identify the EXALT™ using the following procedure codes effective October 1, 2021: XFJB8A7 (Inspection of hepatobiliary duct using single-use duodenoscope, new technology group 7) and XFJD8A7 (Inspection of pancreatic duct using single-use duodenoscope, new technology group 7).

With respect to the cost criterion, the applicant conducted two analyses based on 100 percent of identified claims and 76 percent of identified claims, both of which are further described later in this section. To identify potential cases where EXALT™ could be utilized, the applicant searched the FY 2019 MedPAR file for the following ICD–10–PCS codes:

BILLING CODE 4120–01–P

0F558ZZ	Destruction of right hepatic duct, via natural or artificial opening endoscopic
0F568ZZ	Destruction of left hepatic duct, via natural or artificial opening endoscopic
0F578ZZ	Destruction of common hepatic duct, via natural or artificial opening endoscopic
0F588ZZ	Destruction of cystic duct, via natural or artificial opening endoscopic
0F598ZZ	Destruction of common bile duct, endoscopic
0F5C8ZZ	Destruction of ampulla of vater, endoscopic
0F5D8ZZ	Destruction of pancreatic duct, endoscopic
0F5F8ZZ	Destruction of accessory pancreatic duct, via natural or artificial opening endoscopic
0F758DZ	Dilation of right hepatic duct with intraluminal device, via natural or artificial opening endoscopic
0F758ZZ	Dilation of right hepatic duct , via natural or artificial opening endoscopic
0F768DZ	Dilation of left hepatic duct with intraluminal device, endoscopic
0F768ZZ	Dilation of left hepatic duct, endoscopic
0F778DZ	Dilation of common hepatic duct with intraluminal device, via natural or artificial opening endoscopic
0F778ZZ	Dilation of common hepatic duct, via natural or artificial opening endoscopic
0F788DZ	Dilation of cystic duct with intraluminal device, via natural or artificial opening endoscopic
0F788ZZ	Dilation of cystic duct, endoscopic
0F798DZ	Dilation of common bile duct with intraluminal device, endoscopic
0F798ZZ	Dilation of common bile duct, endoscopic
0F7C8DZ	Dilation of ampulla of vater with intraluminal device, endoscopic
0F7C8ZZ	Dilation of ampulla of vater, endoscopic
0F7D8DZ	Dilation of pancreatic duct with intraluminal device, via natural or artificial opening endoscopic
0F7D8ZZ	Dilation of pancreatic duct, endoscopic
0F7F8DZ	Dilation of accessory pancreatic duct with intraluminal device, endoscopic
0F7F8ZZ	Dilation of accessory pancreatic duct, endoscopic
0FB98ZX	Excision of common bile duct, endoscopic, diagnostic
0FBC8ZX	Excision of ampulla of vater, endoscopic, diagnostic
0FBD8ZX	Excision of pancreatic duct, endoscopic, diagnostic

0FBF8ZX	Excision of accessory pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FC58ZZ	Extirpation of matter from right hepatic duct, via natural or artificial opening endoscopic
0FC68ZZ	Extirpation of matter from left hepatic duct, via natural or artificial opening endoscopic
0FC78ZZ	Extirpation of matter from common hepatic duct, via natural or artificial opening endoscopic
0FC98ZZ	Extirpation of matter from common bile duct, endoscopic
0FCD8ZZ	Extirpation of matter from pancreatic duct, via natural or artificial opening endoscopic
0FCF8ZZ	Extirpation of matter from accessory pancreatic duct, via natural or artificial opening endoscopic
0FF58ZZ	Fragmentation in right hepatic duct, endoscopic
0FF68ZZ	Fragmentation in left hepatic duct, endoscopic
0FF78ZZ	Fragmentation in common hepatic duct, via natural or artificial opening endoscopic
0FF88ZZ	Fragmentation in cystic duct, via natural or artificial opening endoscopic
0FF98ZZ	Fragmentation in common bile duct, endoscopic
0FFC8ZZ	Fragmentation in ampulla of vater, endoscopic
0FFD8ZZ	Fragmentation in pancreatic duct, endoscopic
0FFF8ZZ	Fragmentation in accessory pancreatic duct, via natural or artificial opening endoscopic
0FHB8DZ	Insertion of intraluminal device into hepatobiliary duct, via natural or artificial opening endoscopic
0FHD8DZ	Insertion of intraluminal device into pancreatic duct, endoscopic
0FJB8ZZ	Inspection of hepatobiliary duct, via natural or artificial opening endoscopic
0FJD8ZZ	Inspection of pancreatic duct, endoscopic
0FPB80Z	Removal of drainage device from hepatobiliary duct, via natural or artificial opening endoscopic
0FPB8DZ	Removal of intraluminal device from hepatobiliary duct, via natural or artificial opening endoscopic
0FPD80Z	Removal of drainage device from pancreatic duct, endoscopic
0FPD8DZ	Removal of intraluminal device from pancreatic duct, endoscopic

For the analysis using 100 percent of cases, the applicant identified a total of 59,966 cases spanning 440 MS–DRGs. The applicant then removed 100 percent of charges associated with the service Medical/Surgical Supplies and Devices for the prior technology. The applicant stated that it does not believe use of EXALT™ will replace any other medical supplies but removed 100 percent of charges associated with service category Medical/Surgical Supply Charge Amount, which included the revenue center code 027x, to be as conservative as possible. The applicant then standardized the charges and applied an inflation factor of 13.2 percent, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule, to update the charges from FY 2019 to FY 2021 (85 FR 59039). The applicant added charges for the new technology by multiplying the cost of the technology by the national CCR for implantable devices from the FY 2021 IPPS/LTCH PPS final rule. Under the analysis based on 100 percent of claims, the applicant determined an average case-weighted threshold amount of $66,588 and a final inflated case weighted average standardized charge per case of $96,079.

For the analysis using 76 percent of cases, which the applicant conducted due to these cases mapping to just 14 MS–DRGs, the applicant used the same methodology, which identified 45,530 cases across 14 MS–DRGs. The applicant determined an average case-weighted threshold amount of $63,762 and a final inflated case weighted average standardized charge per case of $84,631. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount for both analyses, the applicant asserted that the technology meets the cost criterion.

We stated in the proposed rule that we are concerned that the applicant used the national CCR for implantable devices from the FY 2021 IPPS/LTCH PPS final rule, as a duodenoscope is not an implantable device. We noted that the cost analysis for another duodenoscope that is the subject of an application for new technology add-on payments for FY 2022, the aScope™ Duodeno, used the national CCR for supplies and equipment to convert the cost of the technology to charges, and that we believe that the same CCR should apply for purposes of the cost analysis for EXALT™ Model D Single-Use Duodenoscope.

We stated that we agreed with the applicant that EXALT™ Model D Single-Use Duodenoscope meets the cost criterion and therefore proposed to approve EXALT™ Model D Single-Use Duodenoscope for new technology add on payments for FY 2022.

As discussed previously, based on the information available at the time of the proposed rule, it appeared that both aScope™ Duodeno and EXALT™ Model D will be identified by the same ICD–10–PCS code and share the same indication for endoscopy and endoscopic surgery within the duodenum. We stated that thus, as we are unable to separately identify these cases to apply two separate payment amounts for these technologies, we were proposing to use a case-weighted average to calculate a single cost that would be used to determine the new technology add-on payment amount for both technologies. To compute the weighted average cost, we summed the total number of projected cases for each of the applicants, which equaled 12,064 (3,750 plus 8,314). Then we divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 31 Percent for aScope™ Duodeno and 69 percent for EXALT™ Model D. We then multiplied the cost per case for the manufacturer specific technology by the case-weighted percentage (0.31 * $1,995 = $620.13 for aScope™ Duodeno and 0.69 * $2,930 = $2,019.23 for EXALT™ Model D). This resulted in a case-weighted average cost of $2,639.36 for both technologies. We invited public comments on the proposed case-weighted average, as well as any alternative approaches for determining and applying the new technology add-on payment amount for cases involving these technologies, for FY 2022.

We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the

lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the product EXALT™ Model D Single-Use Duodenoscope or aScope™ Duodeno would be $1,715.59 for FY 2022 (that is 65 percent of the case-weighted average cost of both technologies).

We invited public comments on whether EXALT™ Model D Single-Use Duodenoscope meets the cost criterion and our proposal to approve new technology add-on payments for EXALT™ Model D Single-Use Duodenoscope for FY 2022. We further invited public comments on our calculation of the maximum new technology add-on payment amount for the EXALT™ Model D.

Comment: A commenter, the applicant, submitted a public comment urging CMS to finalize its proposal to approve an add-on payment for EXALT™ Model D Single-Use Duodenoscope. The commenter agreed that EXALT Model D meets the cost criterion and therefore satisfies the criteria under the alternative new technology pathway for certain transformative new devices finalized by CMS in the FY 2020 IPPS Final Rule. The commenter also supported CMS' proposal to use a case-weighted average to calculate a single cost that would be used to determine the new technology add-on payment amount.

Response: We thank the commenter for its support and feedback.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe EXALT™ Model D meets the cost criterion. Also, EXALT™ Model D received marketing authorization from the FDA on December 13, 2019 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the EXALT™ Model D for FY 2022, and we consider the beginning of the newness period to commence on December 13, 2019 which is when the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation. Based on the information at the time of this final rule, and using the case-weighted average cost as described in the proposed rule and earlier in this final rule, the cost per case of the EXALT™ Model D is $2,639.36. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the EXALT™ Model D Single-Use Duodenoscope or aScope™ Duodeno would be $1,715.59 for FY 2022 (that is 65 percent of the case-weighted average cost of both technologies). Cases involving the use of the EXALT™ Model D eligible for new technology add-on payments will be identified by ICD–10– PCS codes: XFJB8A7 (Inspection of hepatobiliary duct using single-use duodenoscope, new technology group 7) or XFJD8A7 (Inspection of pancreatic duct using single-use duodenoscope, new technology group 7).

(6) FUJIFILM EP–7000X System

Fujifilm Corporation submitted an application for new technology-add on payments for FUJIFILM EP–7000X System for FY 2022. The FUJIFILM EP–7000X system is an endoscopic video imaging system used for endoscopic observation, diagnosis, treatment, and image recording in minimally invasive surgeries of abdominal gynecologic and thoracic areas. Per the applicant, this system allows for the visualization of hemoglobin oxygen saturation levels of blood in superficial tissue under a 2D endoscopic image, which helps physicians identify tissue that is not appropriately oxygenated and thus potentially ischemic. The applicant further explains that the technology consists of four components: Video Laparoscope EL–R740M, Processor VP–7000, Light Source BL–7000X, and Image Processing Unit EX–0.

The FUJIFILM EP–7000X system received Breakthrough Device designation for endoscopic observation, diagnosis, treatment, and image recording in patients requiring such procedures on September 17, 2020 and was granted FDA 510(k) clearance on June 30, 2021. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology and was granted approval to identify the FUJIFILM EP–7000X system using the following procedure codes effective October 1, 2021:

XD2G4V7	Monitoring of upper GI oxygen saturation, percutaneous endoscopic approach, new technology group 7
XD2G8V7	Monitoring of upper GI oxygen saturation, via natural or artificial opening endoscopic, new technology group 7
XD2H4V7	Monitoring of lower GI oxygen saturation, percutaneous endoscopic approach, new technology group 7
XD2H8V7	Monitoring of lower GI oxygen saturation, via natural or artificial opening endoscopic, new technology group 7

With respect to the cost criterion, the applicant searched the FY 2019 MedPAR claims data file to identify potential cases representing patients who may be eligible for treatment with the EP–7000X System. The applicant identified claims that reported an ICD–10–PCS procedure code for gastrointestinal bypass or hernia repair, which the applicant listed in the following table:

0D11476	Bypass upper esophagus to stomach with autologous tissue substitute, percutaneous endoscopic approach
0D11479	Bypass upper esophagus to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1147A	Bypass upper esophagus to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1147B	Bypass upper esophagus to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D114J6	Bypass upper esophagus to stomach with synthetic substitute, percutaneous endoscopic approach
0D114J9	Bypass upper esophagus to duodenum with synthetic substitute, percutaneous endoscopic approach
0D114JA	Bypass upper esophagus to jejunum with synthetic substitute, percutaneous endoscopic approach
0D114JB	Bypass upper esophagus to ileum with synthetic substitute, percutaneous endoscopic approach
0D114K6	Bypass upper esophagus to stomach with nonautologous tissue substitute, percutaneous endoscopic approach
0D114K9	Bypass upper esophagus to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D114KA	Bypass upper esophagus to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D114KB	Bypass upper esophagus to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D114Z6	Bypass upper esophagus to stomach, percutaneous endoscopic approach
0D114Z9	Bypass upper esophagus to duodenum, percutaneous endoscopic approach
0D114ZA	Bypass upper esophagus to jejunum, percutaneous endoscopic approach
0D114ZB	Bypass upper esophagus to ileum, percutaneous endoscopic approach
0D12476	Bypass middle esophagus to stomach with autologous tissue substitute, percutaneous endoscopic approach
0D12479	Bypass middle esophagus to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1247A	Bypass middle esophagus to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1247B	Bypass middle esophagus to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D124J6	Bypass middle esophagus to stomach with synthetic substitute, percutaneous endoscopic approach
0D124J9	Bypass middle esophagus to duodenum with synthetic substitute, percutaneous endoscopic approach
0D124JA	Bypass middle esophagus to jejunum with synthetic substitute, percutaneous endoscopic approach
0D124JB	Bypass middle esophagus to ileum with synthetic substitute, percutaneous endoscopic approach
0D124K6	Bypass middle esophagus to stomach with nonautologous tissue substitute, percutaneous endoscopic approach
0D124K9	Bypass middle esophagus to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D124KA	Bypass middle esophagus to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D124KB	Bypass middle esophagus to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D124Z6	Bypass middle esophagus to stomach, percutaneous endoscopic approach
0D124Z9	Bypass middle esophagus to duodenum, percutaneous endoscopic approach
0D124ZA	Bypass middle esophagus to jejunum, percutaneous endoscopic approach
0D124ZB	Bypass middle esophagus to ileum, percutaneous endoscopic approach
0D13476	Bypass lower esophagus to stomach with autologous tissue substitute, percutaneous endoscopic approach
0D13479	Bypass lower esophagus to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1347A	Bypass lower esophagus to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1347B	Bypass lower esophagus to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D134J6	Bypass lower esophagus to stomach with synthetic substitute, percutaneous endoscopic approach
0D134J9	Bypass lower esophagus to duodenum with synthetic substitute, percutaneous endoscopic approach
0D134JA	Bypass lower esophagus to jejunum with synthetic substitute, percutaneous endoscopic approach
0D134JB	Bypass lower esophagus to ileum with synthetic substitute, percutaneous endoscopic approach
0D134K6	Bypass lower esophagus to stomach with nonautologous tissue substitute, percutaneous endoscopic approach
0D134K9	Bypass lower esophagus to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D134KA	Bypass lower esophagus to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D134KB	Bypass lower esophagus to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D134Z6	Bypass lower esophagus to stomach, percutaneous endoscopic approach
0D134Z9	Bypass lower esophagus to duodenum, percutaneous endoscopic approach
0D134ZA	Bypass lower esophagus to jejunum, percutaneous endoscopic approach
0D134ZB	Bypass lower esophagus to ileum, percutaneous endoscopic approach
0D15476	Bypass esophagus to stomach with autologous tissue substitute, percutaneous endoscopic approach
0D15479	Bypass esophagus to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1547A	Bypass esophagus to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1547B	Bypass esophagus to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D154J6	Bypass esophagus to stomach with synthetic substitute, percutaneous endoscopic approach
0D154J9	Bypass esophagus to duodenum with synthetic substitute, percutaneous endoscopic approach
0D154JA	Bypass esophagus to jejunum with synthetic substitute, percutaneous endoscopic approach
0D154JB	Bypass esophagus to ileum with synthetic substitute, percutaneous endoscopic approach
0D154K6	Bypass esophagus to stomach with nonautologous tissue substitute, percutaneous endoscopic approach

0D154K9	Bypass esophagus to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D154KA	Bypass esophagus to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D154KB	Bypass esophagus to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D154Z6	Bypass esophagus to stomach, percutaneous endoscopic approach
0D154Z9	Bypass esophagus to duodenum, percutaneous endoscopic approach
0D154ZA	Bypass esophagus to jejunum, percutaneous endoscopic approach
0D154ZB	Bypass esophagus to ileum, percutaneous endoscopic approach
0D16479	Bypass stomach to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1647A	Bypass stomach to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1647B	Bypass stomach to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D1647L	Bypass stomach to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D164J9	Bypass stomach to duodenum with synthetic substitute, percutaneous endoscopic approach
0D164JA	Bypass stomach to jejunum with synthetic substitute, percutaneous endoscopic approach
0D164JB	Bypass stomach to ileum with synthetic substitute, percutaneous endoscopic approach
0D164JL	Bypass stomach to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D164K9	Bypass stomach to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D164KA	Bypass stomach to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D164KB	Bypass stomach to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D164KL	Bypass stomach to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D164Z9	Bypass stomach to duodenum, percutaneous endoscopic approach
0D164ZA	Bypass stomach to jejunum, percutaneous endoscopic approach
0D164ZB	Bypass stomach to ileum, percutaneous endoscopic approach
0D164ZL	Bypass stomach to transverse colon, percutaneous endoscopic approach
0D19479	Bypass duodenum to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1947A	Bypass duodenum to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1947B	Bypass duodenum to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D1947L	Bypass duodenum to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D194J9	Bypass duodenum to duodenum with synthetic substitute, percutaneous endoscopic approach
0D194JA	Bypass duodenum to jejunum with synthetic substitute, percutaneous endoscopic approach
0D194JB	Bypass duodenum to ileum with synthetic substitute, percutaneous endoscopic approach
0D194JL	Bypass duodenum to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D194K9	Bypass duodenum to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D194KA	Bypass duodenum to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D194KB	Bypass duodenum to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D194KL	Bypass duodenum to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D194Z9	Bypass duodenum to duodenum, percutaneous endoscopic approach
0D194ZA	Bypass duodenum to jejunum, percutaneous endoscopic approach
0D194ZB	Bypass duodenum to ileum, percutaneous endoscopic approach
0D194ZL	Bypass duodenum to transverse colon, percutaneous endoscopic approach
0D1A47A	Bypass jejunum to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1A47B	Bypass jejunum to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D1A47H	Bypass jejunum to cecum with autologous tissue substitute, percutaneous endoscopic approach
0D1A47K	Bypass jejunum to ascending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1A47L	Bypass jejunum to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1A47M	Bypass jejunum to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1A47N	Bypass jejunum to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1A47P	Bypass jejunum to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1A47Q	Bypass jejunum to anus with autologous tissue substitute, percutaneous endoscopicapproach
0D1A4JA	Bypass jejunum to jejunum with synthetic substitute, percutaneous endoscopic approach
0D1A4JB	Bypass jejunum to ileum with synthetic substitute, percutaneous endoscopic approach
0D1A4JH	Bypass jejunum to cecum with synthetic substitute, percutaneous endoscopic approach
0D1A4JK	Bypass jejunum to ascending colon with synthetic substitute, percutaneous endoscopic approach
0D1A4JL	Bypass jejunum to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1A4JM	Bypass jejunum to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1A4JN	Bypass jejunum to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1A4JP	Bypass jejunum to rectum with synthetic substitute, percutaneous endoscopic approach
0D1A4JQ	Bypass jejunum to anus with synthetic substitute, percutaneous endoscopic approach
0D1A4KA	Bypass jejunum to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KB	Bypass jejunum to ileum with nonautologous tissue substitute, percutaneous endoscopic approach

0D1A4KH	Bypass jejunum to cecum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KK	Bypass jejunum to ascending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KL	Bypass jejunum to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KM	Bypass jejunum to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KN	Bypass jejunum to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KP	Bypass jejunum to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KQ	Bypass jejunum to anus with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4ZA	Bypass jejunum to jejunum, percutaneous endoscopic approach
0D1A4ZB	Bypass jejunum to ileum, percutaneous endoscopic approach
0D1A4ZH	Bypass jejunum to cecum, percutaneous endoscopic approach
0D1A4ZK	Bypass jejunum to ascending colon, percutaneous endoscopic approach
0D1A4ZL	Bypass jejunum to transverse colon, percutaneous endoscopic approach
0D1A4ZM	Bypass jejunum to descending colon, percutaneous endoscopic approach
0D1A4ZN	Bypass jejunum to sigmoid colon, percutaneous endoscopic approach
0D1A4ZP	Bypass jejunum to rectum, percutaneous endoscopic approach
0D1A4ZQ	Bypass jejunum to anus, percutaneous endoscopic approach
0D1B47B	Bypass ileum to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D1B47H	Bypass ileum to cecum with autologous tissue substitute, percutaneous endoscopic approach
0D1B47K	Bypass ileum to ascending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1B47L	Bypass ileum to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1B47M	Bypass ileum to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1B47N	Bypass ileum to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1B47P	Bypass ileum to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1B47Q	Bypass ileum to anus with autologous tissue substitute, percutaneous endoscopic approach
0D1B4JB	Bypass ileum to ileum with synthetic substitute, percutaneous endoscopic approach
0D1B4JH	Bypass ileum to cecum with synthetic substitute, percutaneous endoscopic approach
0D1B4JK	Bypass ileum to ascending colon with synthetic substitute, percutaneous endoscopic approach
0D1B4JL	Bypass ileum to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1B4JM	Bypass ileum to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1B4JN	Bypass ileum to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1B4JP	Bypass ileum to rectum with synthetic substitute, percutaneous endoscopic approach
0D1B4JQ	Bypass ileum to anus with synthetic substitute, percutaneous endoscopic approach
0D1B4KB	Bypass ileum to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KH	Bypass ileum to cecum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KK	Bypass ileum to ascending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KL	Bypass ileum to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KM	Bypass ileum to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KN	Bypass ileum to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KP	Bypass ileum to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KQ	Bypass ileum to anus with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4ZB	Bypass ileum to ileum, percutaneous endoscopic approach
0D1B4ZH	Bypass ileum to cecum, percutaneous endoscopic approach
0D1B4ZK	Bypass ileum to ascending colon, percutaneous endoscopic approach
0D1B4ZL	Bypass ileum to transverse colon, percutaneous endoscopic approach
0D1B4ZM	Bypass ileum to descending colon, percutaneous endoscopic approach
0D1B4ZN	Bypass ileum to sigmoid colon, percutaneous endoscopic approach
0D1B4ZP	Bypass ileum to rectum, percutaneous endoscopic approach
0D1B4ZQ	Bypass ileum to anus, percutaneous endoscopic approach
0D1H47H	Bypass cecum to cecum with autologous tissue substitute, percutaneous endoscopic approach
0D1H47K	Bypass cecum to ascending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1H47L	Bypass cecum to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1H47M	Bypass cecum to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1H47N	Bypass cecum to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1H47P	Bypass cecum to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1H4JH	Bypass cecum to cecum with synthetic substitute, percutaneous endoscopic approach
0D1H4JK	Bypass cecum to ascending colon with synthetic substitute, percutaneous endoscopic approach
0D1H4JL	Bypass cecum to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1H4JM	Bypass cecum to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1H4JN	Bypass cecum to sigmoid colon with synthetic substitute, percutaneous endoscopic approach

0D1H4JP	Bypass cecum to rectum with synthetic substitute, percutaneous endoscopic approach
0D1H4KH	Bypass cecum to cecum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KK	Bypass cecum to ascending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KL	Bypass cecum to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KM	Bypass cecum to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KN	Bypass cecum to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KP	Bypass cecum to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4ZH	Bypass cecum to cecum, percutaneous endoscopic approach
0D1H4ZK	Bypass cecum to ascending colon, percutaneous endoscopic approach
0D1H4ZL	Bypass cecum to transverse colon, percutaneous endoscopic approach
0D1H4ZM	Bypass cecum to descending colon, percutaneous endoscopic approach
0D1H4ZN	Bypass cecum to sigmoid colon, percutaneous endoscopic approach
0D1H4ZP	Bypass cecum to rectum, percutaneous endoscopic approach
0D1K47K	Bypass ascending colon to ascending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1K47L	Bypass ascending colon to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1K47M	Bypass ascending colon to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1K47N	Bypass ascending colon to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1K47P	Bypass ascending colon to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1K4JK	Bypass ascending colon to ascending colon with synthetic substitute, percutaneous endoscopic approach
0D1K4JL	Bypass ascending colon to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1K4JM	Bypass ascending colon to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1K4JN	Bypass ascending colon to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1K4JP	Bypass ascending colon to rectum with synthetic substitute, percutaneous endoscopic approach
0D1K4KK	Bypass ascending colon to ascending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4KL	Bypass ascending colon to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4KM	Bypass ascending colon to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4KN	Bypass ascending colon to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4KP	Bypass ascending colon to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4ZK	Bypass ascending colon to ascending colon, percutaneous endoscopic approach
0D1K4ZL	Bypass ascending colon to transverse colon, percutaneous endoscopic approach
0D1K4ZM	Bypass ascending colon to descending colon, percutaneous endoscopic approach
0D1K4ZN	Bypass ascending colon to sigmoid colon, percutaneous endoscopic approach
0D1K4ZP	Bypass ascending colon to rectum, percutaneous endoscopic approach
0D1L47L	Bypass transverse colon to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1L47M	Bypass transverse colon to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1L47N	Bypass transverse colon to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1L47P	Bypass transverse colon to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1L4JL	Bypass transverse colon to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1L4JM	Bypass transverse colon to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1L4JN	Bypass transverse colon to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1L4JP	Bypass transverse colon to rectum with synthetic substitute, percutaneous endoscopic approach
0D1L4KL	Bypass transverse colon to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1L4KM	Bypass transverse colon to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1L4KN	Bypass transverse colon to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1L4KP	Bypass transverse colon to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1L4ZL	Bypass transverse colon to transverse colon, percutaneous endoscopic approach
0D1L4ZM	Bypass transverse colon to descending colon, percutaneous endoscopic approach
0D1L4ZN	Bypass transverse colon to sigmoid colon, percutaneous endoscopic approach
0D1L4ZP	Bypass transverse colon to rectum, percutaneous endoscopic approach
0D1M47M	Bypass descending colon to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1M47N	Bypass descending colon to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1M47P	Bypass descending colon to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1M4JM	Bypass descending colon to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1M4JN	Bypass descending colon to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1M4JP	Bypass descending colon to rectum with synthetic substitute, percutaneous endoscopic approach
0D1M4KM	Bypass descending colon to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1M4KN	Bypass descending colon to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1M4KP	Bypass descending colon to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1M4Z4	Bypass descending colon to cutaneous, percutaneous endoscopic approach

0D1M4ZM	Bypass descending colon to descending colon, percutaneous endoscopic approach
0D1M4ZN	Bypass descending colon to sigmoid colon, percutaneous endoscopic approach
0D1M4ZP	Bypass descending colon to rectum, percutaneous endoscopic approach
0D1N47N	Bypass sigmoid colon to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1N47P	Bypass sigmoid colon to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1N4JN	Bypass sigmoid colon to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1N4JP	Bypass sigmoid colon to rectum with synthetic substitute, percutaneous endoscopic approach
0D1N4KN	Bypass sigmoid colon to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1N4KP	Bypass sigmoid colon to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1N4ZN	Bypass sigmoid colon to sigmoid colon, percutaneous endoscopic approach
0D1N4ZP	Bypass sigmoid colon to rectum, percutaneous endoscopic approach
0WQF3ZZ	Repair abdominal wall, percutaneous approach
0WQF4ZZ	Repair abdominal wall, percutaneous endoscopic approach
0YQ53ZZ	Repair right inguinal region, percutaneous approach
0YQ54ZZ	Repair right inguinal region, percutaneous endoscopic approach
0YQ63ZZ	Repair left inguinal region, percutaneous approach
0YQ64ZZ	Repair left inguinal region, percutaneous endoscopic approach
0YQ73ZZ	Repair right femoral region, percutaneous approach
0YQ74ZZ	Repair right femoral region, percutaneous endoscopic approach
0YQ83ZZ	Repair left femoral region, percutaneous approach
0YQ84ZZ	Repair left femoral region, percutaneous endoscopic approach
0YQA3ZZ	Repair bilateral inguinal region, percutaneous approach
0YQA4ZZ	Repair bilateral inguinal region, percutaneous endoscopic approach
0YQE3ZZ	Repair bilateral femoral region, percutaneous approach
0YQE4ZZ	Repair bilateral femoral region, percutaneous endoscopic approach
0D18478	Bypass small intestine to small intestine with autologous tissue substitute, percutaneous endoscopic approach
0D184J8	Bypass small intestine to small intestine with synthetic substitute, percutaneous endoscopic approach
0D184K8	Bypass small intestine to small intestine with nonautologous tissue substitute, percutaneous endoscopic approach
0D184Z8	Bypass small intestine to small intestine, percutaneous endoscopic approach

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Per the applicant, oxygen saturation endoscopic imaging would not be necessary, as both imaging procedures are used to evaluate vascular perfusion and therefore the applicant excluded cases with the ICD–10–PCS procedure code 4A1BXSH (Monitoring of Gastrointestinal Vascular Perfusion using Indocyanine Green Dye, External Approach). In addition, the applicant compared cases with procedure code 4A1BXSH to cases without procedure code 4A1BXSH and found that cases with the procedure code have higher total standardized charges. The applicant further limited the cases to MS–DRGs with at least one percent of case volume, leaving 12,020 cases spread across 16 MS–DRGs, or 83 percent of the 14,522 cases initially identified. The applicant standardized the charges and applied an inflation factor of 13.2 percent, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule, to update the charges from FY 2019 to FY 2021 (85 FR 59039). The applicant did not remove charges for the current technology as the applicant believed the use of EP–87000X System would not replace any other therapies except for the vascular perfusion monitoring procedure for which cases were already excluded.

The applicant then added charges for the new technology. The applicant explained that the total cost of the EP–87000X System consists of the capital equipment as well as a service contract for the equipment and a calibration fee required to perform a calibration between a video laparoscope and light source every 6 months. The applicant stated that it calculated the equipment cost per minute using the Medicare physician fee schedule formula used for calculating practice expense relative value units (RVUs). The applicant stated that it also assumed a 3 percent usage rate, a 5.5 percent interest rate, a 0 percent maintenance factor (as the maintenance fee is built into the cost of the equipment), and a 5-year useful life. The applicant multiplied the machine cost per minute by the number of minutes of procedure time, which the applicant estimated to be 4.5 hours or 270 minutes, to obtain the per patient cost. The applicant then converted the cost to charges by dividing the cost per patient by the national average cost-to-charge ratio for supplies and equipment (0.297).

Based on the cost information, the applicant calculated a final inflated case-weighted average standardized charge per case of $106,603 and an average case-weighted threshold of $80,392. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25380), we stated that because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs. We stated that based on preliminary information from the applicant, it appeared that the costs of the FUJIFILM EP–7000X System did not include any operating costs. Therefore, we stated that even if the technology meets the cost criterion, it appeared that no new technology add-on payment would be made for the FUJIFILM EP–7000X System because, as discussed in prior rulemaking and noted previously, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). We invited public comments on whether the

FUJIFILM EP–7000X System has any operating costs. We proposed to approve new technology add-on payments for only the operating costs of FUJIFILM EP–7000X System for FY 2022 if it was determined that the technology does have operating costs, since it appears to meet the cost criterion as previously noted, subject to the technology receiving FDA marketing authorization for endoscopic observation, diagnosis, treatment, and image recording in patients requiring such procedures by July 1, 2021.

Comment: We received one comment from the applicant supporting the FUJIFILM EP–7000X System be approved for new technology add-on payment for FY 2022. The commenter stated that by virtue of the 510(k) clearance (K203717) the FDA marketing authorization is expected by July 15, 2021. Also, the applicant provided updated cost information and stated that the EP–7000X System contains both capital and operating costs. Per the applicant, the capital costs include those associated with the processor, light source, and imaging processing unit, and the operating costs include (1) the flexible endoscope/video laparoscope, which are types of minor equipment treatable as operating costs by hospitals, and (2) the maintenance cost associated with reprocessing and calibration, which are treated as operating expenses by CMS. The commenter asserted that the video laparoscope and flexible endoscope are ''minor equipment'' and, therefore, treatable as an operating cost and not a capital cost. The applicant stated that CMS has a multi-factored test for determining whether a device is minor equipment: (a) In general it has no fixed location and is subject to use by various departments of the provider's facility; (b) it is comparatively small in size and unit cost; (c) it is subject to inventory control; (d) there is a fairly large quantity in use; and, (e) generally, it has a useful life of approximately 3 years or less.[750] Per the applicant, the video laparoscope and flexible endoscope are minor equipment because they are relatively small in size (the video laparoscope is only 330 mm in length), are mobile and not in a fixed location, and may be inventoried separately from other components of the device because they are reprocessed between uses. The applicant further stated that the useful life of the video laparoscope and flexible endoscope is one year, as evidenced by the product warranty of that length of time. Per the applicant, because the video laparoscope and flexible endoscope are integral to the EP–7000X and are treatable as operating costs by virtue of being minor equipment, there are operating costs associated with the technology.

The applicant further stated that the fees and costs associated with reprocessing, sterilization, and maintenance of the device are maintenance fees due to the use of the video laparoscope and flexible endoscope for more than one patient and are also not considered to be capital costs.[751]

Response: We thank the applicant for their comment. However, we remain concerned that the cost for FUJIFILM EP–7000X System includes only capital-related costs and does not include operating costs. We note that the flexible endoscope is not included on the Breakthrough Device designation and is therefore ineligible for new technology add-on payments under the alternative pathway, and the remainder of our response refers only to the video laparoscope listed on the Breakthrough Device designation. We agree that minor equipment, as determined by the multi-factor test described in the Provider Reimbursement Manual (PRM) above, can be considered to be operating costs in some cases. Though the applicant asserts that the technology meets the criteria to be considered minor equipment, we disagree that the useful life of a technology is evidenced by its warranty, and believe that the useful life described in the criteria would extend for many years past that, particularly in the case of scopes. Since we believe that the video laparoscope would have a useful life extending past 3 years, we cannot consider it to be treatable as operating costs as it is not minor equipment. We further note that the PRM states that items that have a standalone functional capability may be considered on an item-by-item basis, but items purchased as in integrated system must be considered as a single asset when applying the capitalization threshold.[752] Since the video laparoscope does not have a standalone functional capacity as it requires connections to the capital components of the system (that is, light source, processor) to function, we consider the FUJIFILM EP–7000x System to be capital as it is an integrated system and believe we should not separate individual components of the system for the purposes of determining whether it includes operating costs.

In addition, while we agree with the applicant's assertion that maintenance and processing fees are considered operating expenses, when determining a new technology add-on payment, we provide payment based on the cost of the actual technology (such as the drug or device itself) and not for additional costs related to the use of the device, such as the ongoing use of the device including maintenance and processing fees. For example, if a technology required an extra hour of operating room time, or reduced the amount of procedure time, we would neither add nor deduct costs based on this, and would only consider the actual cost of the technology at the time of purchase in our determination of the add-on payment. Therefore, the maintenance and processing fees described by the applicant are not eligible to be included in new technology add-on payments.

Based on the above, we continue to believe that there are no operating costs with the use of the FUJIFILM EP–7000X System. Therefore, we are not approving new technology add-on payments for the FUJIFILM EP–7000X System for FY 2022.

(7) Harmony™ Transcatheter Pulmonary Valve (TPV) System

Medtronic submitted an application for new technology-add on payments for Harmony™ Transcatheter Pulmonary Valve (TPV) System (''Harmony™'') for FY 2022. The system consists of a bioprosthetic heart valve developed from porcine pericardial tissue mounted on self-expanding nitinol struts sewn to a polyester fabric. According to the applicant, Harmony™ is implanted in the patient's heart between the right ventricle and the bifurcation of the pulmonary arteries to treat patients with congenital heart disease who are indicated for a pulmonary valve replacement. The applicant states that Harmony™ is the first transcatheter pulmonary valve that is designed to treat the patient's condition at the native site of the pulmonary valve without a pre-existing valve conduit or pre-existing bioprosthetic valve.

The Harmony™ TPV System received designation as a Breakthrough Device on May 1, 2019, with the indication for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired right ventricular outflow tract. In the proposed rule, we stated that the applicant noted that the proposed indication for the FDA marketing authorization would be more expansive than the indication for the FDA

[750] Provider Reimbursement Manual (PRM) Part 1, ch. 1, § 104.5.

[751] Provider Reimbursement Manual (PRM), Part 1, ch. 28 § 2806.2.

[752] PRM, Part1, ch. 1, § 108.1.

Breakthrough Device status, to include patients who have had a prior transcatheter intervention. We noted that under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of the Harmony™ TPV System for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired RVOT, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022. Subsequently, the applicant received Premarket Approval (PMA) as a Class III medical device on March 26, 2021 with an indication for use in the management of pediatric and adult patients with severe pulmonary regurgitation (that is, severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction ≥30% as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement. Since the Breakthrough Device designation is indicated for use in patients with a surgically-repaired RVOT, and does not include patients with a native RVOT, we note that only the Breakthrough Device indication is eligible for new technology add-on payments.

The applicant noted that the Harmony™ TPV System is currently reported within table 02R of the ICD–10 PCS tabular list (body part value Pulmonary Valve, approach value Percutaneous, device value as appropriate, and qualifier value No Qualifier). Per the applicant, this same code also applies to existing technology for transcatheter valve replacement within a conduit or a pre-existing prosthetic valve. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology and was granted approval to identify the Harmony™ Transcatheter Pulmonary Valve (TPV) using the following procedure code effective October 1, 2021: 02RH38M (Replacement of pulmonary valve with zooplastic tissue, native site, percutaneous approach).

With respect to the cost criterion, the applicant searched the FY 2019 MedPAR dataset for claims representing patients with congenital diagnoses who received a surgical valve or a transcatheter procedure. The applicant identified claims across five MS–DRGs after excluding cases with outlier payments. Per the applicant, 6 percent of cases were in MS–DRG 216, 24 percent of cases were in MS–DRG 219, 12 percent of cases were in MS–DRG 220, 26 percent of cases were in MS–DRG 266, and 32 percent of cases were in MS–DRG 267. The applicant did not provide case counts because the volume in each MS–DRG was fewer than 11 cases.

Next, the applicant removed charges for the prior technology and standardized the charges. The applicant described the charges for the technology that would be replaced as ''the sum of the medical-surgical pacemaker amount, the intraocular lens amount, the other implants amount, and the investigational device amount.'' The applicant also removed charges related to the prior technology, which it described as ''the sum of the medical surgical supplies amount, the durable medical equipment amount, and the used durable medical amount minus the prior technology charges.'' The applicant then applied an inflation factor of 13.1 percent, which per the applicant is the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule, to update the charges from FY 2019 to FY 2021. We note that the applicant appears to have used the FY 2021 IPPS/LTCH PPS proposed rule inflation factor rather than the 2-year inflation factor from the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent (85 FR 59039), which would have resulted in a higher inflated charge figure. The applicant added charges for the new technology by dividing the cost of the Harmony™ TPV by the national CCR for implantable devices, which is 0.293 (85 FR 58601). The applicant also added charges related to the new technology, which the applicant estimated to be similar to the charges related to transcatheter procedures within MS–DRGs 266–267.

The applicant calculated a final inflated case-weighted average standardized charge per case of $257,970 and an average case-weighted threshold of $202,037. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25381), we expressed our concern that the applicant's charge threshold analysis utilized a small sample of 55 cases, given that the applicant projected a case volume of over 1,000 cases for FY 2022. Subject to the applicant adequately addressing this concern, we stated that we would agree that the technology meets the cost criterion and therefore are proposing to approve Harmony™ Transcatheter Pulmonary Valve (TPV) System for new technology add-on payments for FY 2022, subject to the technology receiving FDA marketing authorization for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired right ventricular outflow tract by July 1, 2021. We stated that, as noted previously, only the use of the Harmony™ TPV System for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired right ventricular outflow tract, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of the Harmony™ Transcatheter Pulmonary Valve (TPV) System is $41,500. Per the applicant, this cost is comprised of $33,000 for the Harmony™ TPV and $8,500 for the Harmony™ transcatheter pulmonary valve delivery and loading system. We stated that it was not clear to us whether these costs reflect the use of capital equipment. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. We stated as a result, if both components of the Harmony™ Transcatheter Pulmonary Valve (TPV) System are operating costs, we were proposing that the maximum new technology add-on payment for a case involving the use of the Harmony™ Transcatheter Pulmonary Valve (TPV) System would be $26,975 for FY 2022 (that is 65 percent of the average cost of the technology).

We invited public comments on whether the Harmony™ Transcatheter Pulmonary Valve (TPV) System meets the cost criterion and our proposal to approve new technology add-on payments for Harmony™ Transcatheter Pulmonary Valve (TPV) System for FY 2022, subject to FDA marketing authorization of Harmony™ Transcatheter Pulmonary Valve (TPV) System by July 1, 2021 for the treatment of patients with severe pulmonary regurgitation who have had prior intervention on the right ventricular outflow tract and are clinically indicated for a pulmonary valve

replacement. We also invited public comment on whether the costs of the Harmony™ TPV and Harmony™ transcatheter pulmonary valve delivery and loading system reflect use of capital equipment.

Comment: The applicant submitted a public comment urging CMS to finalize its proposal to approve a new technology add-on payment for Harmony™ Transcatheter Pulmonary Valve (TPV) System. The commenter noted that the proposed rule referred to the anticipated FDA approval of the technology as 510(k) clearance instead of premarket approval application (PMA). The commenter also requested that CMS consider that because FDA grants Breakthrough Device designation early in the product development process, the final indication for a product may evolve based on clinical research findings, and therefore may not be identical to the proposed indication wording at the time the designation is granted. In the specific case of the Harmony™ TPV System, the applicant stated that the final commercial indication differs from the Breakthrough Device designation in that it also includes use in native right ventricular outflow tracts in addition to surgically-repaired right ventricular outflow tracts. The applicant further stated that the final approval reflects a single, ongoing development and review process, which is distinct from scenarios in which a manufacturer may submit additional indications for separate reviews and approvals/clearances that are not encompassed by the single process arising from the Breakthrough Device designation. Accordingly, it requested that the new technology add-on payment eligibility apply to the full FDA-approved indication for the Harmony™ TPV System.

With respect to the concerns for the cost criterion that the charge threshold analysis conducted for the Harmony™ TPV System utilized a small sample of 55 cases, while their projected case volume was over 1,000 cases for FY 2022 (86 FR 25381) the applicant clarified that the projected sales volume of 1,054 that was included in the application included patients across payer types, while the cost criterion analysis was based on Medicare claims data only. The applicant stated that it was indicated in the application, based on analysis of the Nationwide Inpatient Sample (NIS) dataset, which is part of the Healthcare Cost and Utilization Project sponsored by the Agency for Healthcare Research and Quality, that approximately 16 percent of the total number of patients with the relevant congenital heart disease diagnosis codes (selected based on the patients enrolled in the Harmony™ feasibility and IDE studies) were Medicare beneficiaries. The commenter applied this percentage to the projected sales volume of 1,054 to project the anticipated Medicare volume to be 171 patients. While the projected Medicare volume of 171 still exceeds the cases found in the historical claims data for the target patient population, the applicant stated it is directionally more consistent than the figure of over 1,000 cases, about which CMS expressed concern in the proposed rule. The applicant further stated that because Harmony™ represents a new, less invasive treatment option for patients, it is reasonable to expect that more interventions may be performed in the future than what is currently reflected by the number of cases in the historical claims data.

With respect to the concern that the costs of Harmony™ TPV may include capital costs, the applicant stated that they can confirm that neither of the components listed are considered capital equipment, as both the bioprosthetic heart valve and the delivery system are single-use products. The applicant stated that specifically, the bioprosthetic valve is implanted in the patient's heart where it remains, and the delivery system delivers the valve to the heart and is then discarded after a single use.

Response: We thank the commenter for the additional information and feedback. We agree that the FDA approval of the technology should be listed as a premarket approval application (PMA) and in this final rule, have revised the description of the relevant approval to indicate that the applicant received Premarket Approval (PMA) as a Class III medical device on March 26, 2021. With regard to the differences between the Breakthrough Device designation indication and the PMA indication, under § 412.87(c)(1), a new medical device under the alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation (85 FR 58736). Since the PMA indication is broader than the Breakthrough Device indication in that it includes native outflow tracts in addition to surgically-repaired outflow tracts, only the Breakthrough Device indication is applicable for purposes of new technology add-on payments.

Regarding the cost criterion, we thank the applicant for its explanation of the discrepancy between the projected sales volume and the anticipated Medicare volume. We also agree with the applicant that both the bioprosthetic heart valve and the delivery system are single-use products and that these components are not capital costs.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe Harmony™ Transcatheter Pulmonary Valve (TPV) System meets the cost criterion. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Harmony™ Transcatheter Pulmonary Valve (TPV) System for FY 2022, and we consider the beginning of the newness period to commence on March 26, 2021, which is when the technology received FDA marketing authorization for use in the management of pediatric and adult patients with severe pulmonary regurgitation (that is, severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction ≥30% as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement. As previously discussed, under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of the Harmony™ TPV System for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired RVOT, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022. Since the Breakthrough Device designation is indicated for use in patients with a surgically-repaired RVOT, and does not include patients with a native RVOT, only cases involving the Breakthrough Device indication for use in patients with a surgically-repaired RVOT are eligible for new technology add-on payments.

Based on the information at the time of this final rule, the cost per case of the Harmony™ Transcatheter Pulmonary Valve (TPV) System is $41,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Harmony™ Transcatheter Pulmonary Valve (TPV) System would be $26,975 for FY 2022 (that is 65 percent of the average cost of the technology). Cases involving the use of the Harmony™ Transcatheter Pulmonary Valve (TPV) System that are

eligible for new technology add-on payments will be identified by ICD–10–PCS code 02RH38M (Replacement of pulmonary valve with zooplastic tissue, native site, percutaneous approach).

(10) INTERCEPT Fibrinogen Complex (PRCFC)

Cerus Corporation applied for new technology-add on payments for INTERCEPT Fibrinogen Complex (pathogen reduced cryoprecipitated fibrinogen complex), for FY 2022. INTERCEPT Fibrinogen Complex is a blood product indicated for the treatment for fibrinogen deficiency-related bleeding, including massive hemorrhage. Per the applicant, this blood product is useful in emergency departments and operating rooms due to its 5-day shelf life at room temperature. The applicant stated that the 5-day shelf life of the blood product makes it immediately available in a ready-to-transfuse form as a fibrinogen source and thereby provides a significant benefit for patients with massive hemorrhage in a real time-critical fashion that is not achievable with other existing fibrinogen replacement products.

INTERCEPT Fibrinogen Complex is designated as a Breakthrough Device, indicated for control of massive bleeding associated with fibrinogen (Fg) deficiency, and received FDA premarket approval (PMA) on November 24, 2020 for the following indications: (1) Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency; (2) control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available; (3) second-line therapy for von Willebrand disease (vWD); and (4) control of uremic bleeding after other treatment modalities have failed. The applicant provided information stating that the product was not available for sale until May 5, 2021 due to manufacturing lead time for system components as well as validations and quality control analyses that needed to be completed by the manufacturing facilities and delayed production of commercially available product. We note that, under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of INTERCEPT Fibrinogen Complex for the control of massive bleeding associated with fibrinogen (Fg) deficiency, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022.

The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology and was granted approval to identify INTERCEPT Fibrinogen Complex using the following procedure codes effective October 1, 2021: 30233D1 (Transfusion of nonautologous pathogen reduced cryoprecipitated fibrinogen complex into peripheral vein, percutaneous approach) and 30243D1 (Transfusion of nonautologous pathogen reduced cryoprecipitated fibrinogen complex into central vein, percutaneous approach).

With respect to the cost criterion, the applicant searched the FY 2019 MedPAR dataset for cases reporting an ICD–10–PCS procedure code for nonautologous plasma cryoprecipitate. The applicant identified 8,553 cases spanning over 369 MS–DRGs.

30230M1	Transfusion of nonautologous plasma cryoprecipitate into Peripheral vein, open approach
30233M1	Transfusion of nonautologous plasma cryoprecipitate into peripheral vein, percutaneous approach
30240M1	Transfusion of nonautologous plasma cryoprecipitate into central vein, open approach
30243M1	Transfusion of nonautologous plasma cryoprecipitate into Central vein, percutaneous approach
30250M1	Transfusion of nonautologous plasma cryoprecipitate into peripheral artery, open approach
30253M1	Transfusion of nonautologous plasma cryoprecipitate into peripheral artery, percutaneous approach
30260M1	Transfusion of nonautologous plasma cryoprecipitate into central artery, open approach
30263M1	Transfusion of nonautologous plasma cryoprecipitate into central artery, percutaneous approach
30273M1	Transfusion of nonautologous plasma cryoprecipitate into products of conception, circulatory, percutaneous approach
30277M1	Transfusion of nonautologous plasma cryoprecipitate into products of conception, circulatory, via natural or artificial open approach

Per the applicant, the top 5 MS–DRGs were 219 (Cardiac Valve and Other Major Cardiothoracic Procedures Without Cardiac Catheterization with MCC), 220 (Cardiac Valve and Other Major Cardiothoracic Procedures Without Cardiac Catheterization with CC), 871 (Septicemia or Severe Sepsis Without Mv >96 Hours with MCC), 003 (ECMO or Tracheostomy with Mv >96 Hours Or Principal Diagnosis Except Face, Mouth And Neck With Major O.R. Procedure), and 216 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC) and accounted for 34 percent of all cases. The applicant then removed charges for the technology being replaced. Per the applicant, INTERCEPT Fibrinogen Complex would replace the current nonautologous plasma cryoprecipitate billed with a blood revenue code. The applicant explained that it could not separate nonautologous plasma cryoprecipitate from other blood charges and therefore removed all charges from the blood department. The applicant then standardized the charges and applied the 2-year outlier inflation factor of 13.2 percent used to update the outlier threshold in the FY 2021 IPPS/LTCH final rule (85 FR 59039). To estimate the cost of the technology, the applicant multiplied the sale price of INTERCEPT Fibrinogen Complex by an average of 12.9 units of cryoprecipitate required per patient, which the applicant asserted as equivalent to 5.2 grams of fibrinogen based on a recent study in adult cardiac surgery patients with clinically significant bleeding and fibrinogen deficiency.[753] The applicant estimated an average per-patient cost of $3,900, which the applicant converted to charges using the national cost-to-charge ratio for blood and blood products (0.271) from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). The applicant indicated that the outlier inflation factor was not applied to charges for INTERCEPT Fibrinogen Complex.

The applicant calculated a final inflated case-weighted average standardized charge per case of $299,895 and an average case-weighted threshold of $183,897. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25385), we agreed with the applicant that INTERCEPT Fibrinogen Complex meets the cost criterion and therefore proposed to approve INTERCEPT Fibrinogen

[753] Callum J. et al. (2019). Effect of fibrinogen concentrate vs cryoprecipitate on blood component transfusion after cardiac surgery: The FIBRES randomized clinical trial. *JAMA, 322*(20), 1–11.

Complex for new technology add-on payments for FY 2022 when used for the control of massive bleeding associated with fibrinogen (Fg) deficiency. Based on preliminary information from the applicant at the time of the proposed rule, the cost of INTERCEPT Fibrinogen Complex is $750 per gram × 5.2 grams for the amount of $3,900 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of INTERCEPT Fibrinogen Complex would be $2,535 per patient for FY 2022 (that is, 65 percent of the average cost of the technology).

We invited public comments on whether INTERCEPT Fibrinogen Complex meets the cost criterion and our proposal to approve new technology add-on payments for INTERCEPT Fibrinogen Complex for FY 2022 when used for the control of massive bleeding associated with fibrinogen (Fg) deficiency.

Comment: Several commenters, including the applicant, urged CMS to finalize our proposal to approve a new technology add-on payment for INTERCEPT Fibrinogen Complex. The applicant also requested that CMS include the commercial name for the technology, INTERCEPT Fibrinogen Complex, in the final rule so that providers understand that pathogen reduced cryoprecipitated fibrinogen complex (PRCFC) and INTERCEPT Fibrinogen Complex are the same product.

Response: We thank the commenters for their support and feedback and note that we have included the commercial name for INTERCEPT Fibrinogen Complex in this final rule.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe INTERCEPT Fibrinogen Complex meets the cost criterion. Also, the applicant received FDA marketing authorization on November 24, 2020 for the following indications: (1) Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency; (2) control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available; (3) second-line therapy for von Willebrand disease (vWD); and (4) control of uremic bleeding after other treatment modalities have failed. Therefore, we are finalizing our proposal to approve new technology add-on payments for INTERCEPT Fibrinogen Complex for FY 2022, and we consider the beginning of the newness period to commence on May 5, 2021, based on information provided by the applicant that the product first became available for sale on that date. We note that, under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of INTERCEPT Fibrinogen Complex for the treatment of massive bleeding associated with fibrinogen (Fg) deficiency, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022. Since the Breakthrough Device designation is indicated for use in the treatment of massive bleeding associated with fibrinogen (Fg) deficiency, and not for the other uses under the FDA marketing authorization, only cases involving the use of INTERCEPT Fibrinogen Complex for the Breakthrough Device indication for use in the treatment of massive bleeding associated with fibrinogen (Fg) deficiency are eligible for new technology add-on payments.

Based on the information at the time of this final rule, the cost per case of the INTERCEPT Fibrinogen Complex is $3,900. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of INTERCEPT Fibrinogen Complex, is $2,535 for FY 2022 (that is 65 percent of the average cost of the technology). Cases involving the use of the INTERCEPT Fibrinogen Complex that would be eligible for new technology add-on payments will be identified by ICD–10–PCS codes: 30233D1 (Transfusion of nonautologous pathogen reduced cryoprecipitated fibrinogen complex into peripheral vein, percutaneous approach) or 30243D1 (Transfusion of nonautologous pathogen reduced cryoprecipitated fibrinogen complex into central vein, percutaneous approach), in combination with one of the following ICD–10–CM codes: D65 (Disseminated intravascular coagulation) or D68.2 (Hereditary deficiency of other clotting factors).

(11) RECELL® Autologous Cell Harvesting Device

Avita Medical submitted an application for new technology-add on payments for RECELL® Autologous Cell Harvesting Device (RECELL®). The device is a standalone, single-use, battery-powered device used to process an autologous skin cell suspension for the treatment of acute thermal burn wounds. Per the applicant, the purpose of the device is to assist with harvesting a small graft from the patient's healthy skin and immediate processing into an autologous skin cell suspension which is then immediately applied to the patient's burn wound following surgical preparation of the acute thermal burn wound. The applicant describes the device components as including a mechanical scraping tray, wells for incubating the donor graft with a proprietary enzyme solution, a rinsing well, a cell strainer, a spray applicator as well as buttons for ''self-test'', and ''run.''

RECELL® was granted Expedited Access Pathway (EAP) by FDA (and is therefore considered part of the Breakthrough Devices Program by FDA [754] on December 10, 2015 with the indication for use at the patient's point-of care for preparation of an autologous epithelial cell suspension to be applied to a prepared wound bed; under the supervision of a healthcare professional, the suspension is used to achieve epithelial regeneration for definitive closure of burn injuries, particularly in patients having limited availability of donor skin for autografting. RECELL® received FDA premarket approval (PMA) on September 20, 2018 with the indication for use listed as indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. We stated in the proposed rule that since the narrower indication for which the technology received PMA is included within the scope of the EAP indication, it appears that the PMA indication is appropriate for new technology add-on payment under the alternative pathway criteria. Per the applicant, RECELL® was available for sale upon FDA approval, albeit on a very limited basis primarily to burn centers involved with the clinical trials. According to the applicant, new ICD–10–PCS codes that are specific to RECELL® were created effective October 1, 2019. Per the applicant, the first three characters of these codes are ''0HR,'' followed by a fourth character signifying which body part is impacted, then ''X72'' for the final three characters.

With regard to the newness criterion, we stated that we believe that the beginning of the newness period for RECELL® commences from the date of

[754] *https://www.fda.gov/regulatory-information/search-fida-guidance-documents/breakthrough-devices-program.*

approval by the FDA on September 20, 2018, as the applicant indicated the technology was available for sale from that date. Because the 3-year anniversary date of the entry of RECELL® onto the U.S. market (September 20, 2021) will occur in FY 2021, we stated that we do not believe that the device is eligible for new technology add on payments for FY 2022. Accordingly, we proposed to disapprove RECELL® Autologous Cell Harvesting Device for new technology add on payments for FY 2022. We invited public comments on our proposal to disapprove new technology add-on payments for the RECELL Autologous Cell Harvesting Device for FY 2022, including on whether the technology meets the newness criterion.

Comment: The applicant submitted a comment in response to our concerns. The applicant asserted that the eligibility date for the newness criterion for RECELL® should be the date on which inpatient coding was available for the technology. Since the unique Cell Suspension Technique ICD–10 code qualifier describing RECELL® did not go into effect until October 1, 2019, the applicant asserts that should be the date considered for new technology add-on payment eligibility purposes and not the date of FDA approval on September 20, 2018. The applicant explains that the regulation at 42 CFR 412.87(c) states that under the alternative pathway, the newness period begins after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). The applicant emphasized that the regulatory section does not reference the FDA approval date, which it stated is appropriate because there is typically a lag between FDA approval and assignment of codes for the technology. Additionally, the applicant stated that our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology (88 FR 25211). Also, the applicant stated CMS proposed to extend new technology add-on payment status for numerous technologies that were cleared by FDA on dates earlier than the RECELL approval date. The applicant believes it would be inconsistent and arbitrary for CMS to deny new technology add-on payments for RECELL in FY 2022 on the basis of the FDA clearance date while extending new technology add-on payment status to technologies that are less ''new'' than RECELL®. Therefore the applicant believes RECELL® should qualify for new technology add-on payment in FY 2022.

We also received several comments reiterating the applicant's comments. The commenters also added that they are requesting approval of new technology add-on payment for RECELL due to the clinically meaningful improvements in healing they observed in their patients, in order to make it financially viable to provide to patients.

Response: We thank the applicant and the other commenters for their comments. However, we disagree that the newness date should begin with the date that the unique ICD–10–PCS code describing RECELL® was effective on October 1, 2019 and not with the date of FDA approval, September 20, 2018. We note that in the FY 2005 final rule (69 FR 49002), we provided a detailed explanation for why using the date on which a specific code is assigned to a technology is not an appropriate test of newness. In that rule, we noted that, in many instances, a technology may have been in use for several years, or even several decades, prior to the assignment of a new code (69 FR 49003). Thus, we continue to believe it is appropriate to determine newness based on the date on which a product becomes available for use in the Medicare population and the date when hospitals can begin to use either an existing or new code to bill for the new service or technology. Consistent with the statute and our implementing regulations, a technology is no longer considered as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). As such, in this case, because RECELL has been available on the U.S. market for more than 2 to 3 years, we consider the costs to have been included in the MS–DRG relative weights. In addition, although we are finalizing our proposal to extend new technology add-on payments for technologies with a newness date prior to RECELL®, this policy does not extend to technologies that were not approved for new technology add-on payments for FY 2021. We note that our process requires applicants to submit their application for new technology add-on payments by the appropriate deadlines for the fiscal year in which they wish to be granted new technology status. We further note that the applicant received FDA approval on September 20, 2018 and could have submitted an application for new technology add on payments for earlier fiscal years under either the traditional or alternative pathways. The applicant did not apply for and was not approved for new technology add on payments for FY 2021. Our proposal was limited to an extension of new technology add-on payments for previously approved technologies and not to grant a new approval for add-on payments, and therefore RECELL® does not fit within the parameters of this proposal. We do not believe it would be appropriate to grant RECELL® a new technology add-on payment when it is not new for the fiscal year for which it is applying.

Therefore, for the reasons stated in the proposed rule and in this final rule, because the RECELL® Autologous Cell Harvesting Device will not be within the newness period for FY 2022 and is therefore ineligible to receive new technology add-on payments, we are not approving new technology add-on payments for the RECELL® Autologous Cell Harvesting Device for FY 2022. As discussed previously, our past and present practice is to analyze the new technology add-on payment criteria in a sequential fashion, beginning with newness. We note that the applicant submitted a comment in regard to the cost criterion. However, as RECELL® does not meet the criterion for newness, we will not be making a determination in regard to cost or summarizing comments on the cost criterion in this final rule.

(12) Shockwave C2 Intravascular Lithotripsy (IVL) System

Shockwave Medical Inc. submitted an application for new technology-add on payments for Shockwave C2 Intravascular Lithotripsy (IVL) System for FY 2022. Per the applicant, the IVL Catheter is intended for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting. The applicant explained that the device is delivered through the coronary arterial system, and it generates intermittent sonic waves within the target treatment site that disrupt calcium within the lesion, allowing subsequent dilation of a coronary artery stenosis using low balloon pressure. The applicant also noted that the procedure can be used for otherwise difficult to treat calcified stenosis, including calcified stenosis that are anticipated to exhibit resistance to full balloon dilation or subsequent uniform coronary stent expansion.

Shockwave C2 Intravascular Lithotripsy (IVL) System was designated as a Breakthrough Device in August 2019, indicated for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting.

The applicant received Pre-Market Approval as a Class III device from the FDA on February 12, 2021 for the same proposed indication. The applicant stated that though they expected market availability by April 2021, the device became available immediately after FDA approval. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology and was granted approval to identify the Shockwave C2 Intravascular Lithotripsy (IVL) System using the following procedure codes effective October 1, 2021:

02F03ZZ	Fragmentation in coronary artery, one artery, percutaneous approach
02F13ZZ	Fragmentation in coronary artery, two arteries, percutaneous approach
02F23ZZ	Fragmentation in coronary artery, three arteries, percutaneous approach
02F33ZZ	Fragmentation in coronary artery, four or more arteries, percutaneous approach

With regard to the cost criterion, the applicant conducted two analyses based on 100 percent of identified claims and 81 percent of identified claims. To identify potential cases where Coronary IVL could be utilized, the applicant searched the FY 2019 MedPAR file for ICD–10–PCS codes for the placement of a coronary stent, consistent with the anticipated FDA indication for Shockwave C2 Intravascular Lithotripsy (IVL). The applicant included all codes beginning with ''027'' and ending with ''6'' or Z'' in its search. The applicant highlighted the potential codes in between using the table that follows:

Section: 0 Medical and Surgical
Body System: 2 Heart and Great Vessels
Operation: 7 Dilation: expanding an orifice or the lumen of a tubular body part

Body Part	Approach	Device	Qualifier
0 Coronary Artery, One Artery **1 Coronary Artery, Two Arteries** **2 Coronary Artery, Three Arteries** **3 Coronary Artery, Four or More Arteries**	0 Open **3 Percutaneous** 4 Percutaneous Endoscopic	**4 Intraluminal Device, Drug-eluting** **2 Intraluminal Device, Drug-eluting, Two** **3 Intraluminal Device, Drug-eluting, Three** **4 Intraluminal Device, Drug-eluting, Four or More** **D Intraluminal Device** **E Intraluminal Device, Two** **F Intraluminal Device, Three** **G Intraluminal Device, Four or More** T Intraluminal Device, Radioactive Z No Device	**5 Bifurcation** **6** Z No Qualifier

For the analysis using 100 percent of cases, the applicant identified 160,901 cases mapping to 209 MS–DRGs. Per the applicant, Shockwave C2 Intravascular Lithotripsy (IVL) does not replace any current devices used for indicated patients. However, to be conservative, the applicant removed 50 percent of charges associated with revenue center 0278—other implants. The applicant then standardized the charges and applied the 2-year outlier inflation factor of 13.2 percent used to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039), to update the charges from FY 2019 to FY 2021. The applicant added charges for the new technology by multiplying the cost of the technology by the estimated number of devices per patient and then dividing by the national CCR for implantable devices (0.293) from the FY 2021 IPPS/LTCH PPS final rule. Under the analysis based on 100 percent of identified claims, the applicant calculated a final inflated case-weighted average standardized charge per case of $143,805 and an average case-weighted threshold of $115,693.

For the analysis using 81 percent of cases, the applicant identified 130,907 cases mapping to MS–DRGs 246 and 247. The applicant conducted the same analysis noted previously and determined a final inflated case-weighted average standardized charge per case of $122,020 and an average case-weighted threshold of $104,783. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25389), we agreed with the applicant that Shockwave C2 Intravascular Lithotripsy (IVL) System meets the cost criterion and therefore proposed to approve Shockwave C2 Intravascular Lithotripsy (IVL) System for new technology add on payments for FY 2022, subject to the technology receiving FDA marketing authorization for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting by July 1, 2021.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of the Shockwave C2 Intravascular Lithotripsy (IVL) System is $4,700 per device × 1.2 devices required per case for an amount of $5,640. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the Shockwave C2 Intravascular Lithotripsy (IVL) System would be $3,666 for FY 2022 (that is, 65 percent of the average cost of the technology).

We invited public comments on whether the Shockwave C2 Intravascular Lithotripsy (IVL) System meets the cost criterion and our proposal to approve new technology add-on payments for the Shockwave C2 Intravascular Lithotripsy (IVL) System for FY 2022, subject to Shockwave C2 Intravascular Lithotripsy (IVL) System receiving FDA marketing authorization by July 1, 2021 for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting.

Comment: The applicant submitted a public comment expressing support for the approval of the Shockwave C2 Intravascular Lithotripsy (IVL) System for the new technology add-on payment for FY 2022. The applicant further stated that the device became commercially available approximately two weeks after the date of FDA approval.

Response: We thank the commenter for their support and for providing additional information. We note that we had previously received communication from the applicant stating that the device was commercially available immediately after FDA approval and therefore, absent additional information, it is unclear which is the date of commercial availability. However, we note that, using either date as the beginning of the newness period, the technology would be considered new for FY 2022.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe Shockwave C2 Intravascular Lithotripsy (IVL) System meets the cost criterion. Shockwave C2 Intravascular Lithotripsy (IVL) System received marketing authorization from the FDA on February 12, 2021 for the indications covered by its Breakthrough Device designation for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Shockwave C2 Intravascular Lithotripsy (IVL) System for FY 2022, and we consider the beginning of the newness period to commence on February 12, 2021 which is the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information at the time of this final rule, the cost per case of the Shockwave C2 Intravascular Lithotripsy (IVL) System is $4,700 per device × 1.2 devices required per case for an amount of $5,640. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Shockwave C2 Intravascular Lithotripsy (IVL) System is $3,666 for FY 2022 (that is 65 percent of the average cost of the technology). Cases involving the use of the Shockwave C2 Intravascular Lithotripsy (IVL) System that are eligible for new technology add-on payments will be identified by ICD–10– PCS codes:

02F03ZZ	Fragmentation in coronary artery, one artery, percutaneous approach
02F13ZZ	Fragmentation in coronary artery, two arteries, percutaneous approach
02F23ZZ	Fragmentation in coronary artery, three arteries, percutaneous approach
02F33ZZ	Fragmentation in coronary artery, four or more arteries, percutaneous approach

b. Alternative Pathways for Qualified Infectious Disease Products (QIDPs)

(1) CONTEPO™ (fosfomycin)

Nabriva Therapeutics US, Inc. submitted an application for new technology-add on payments for CONTEPO™ (fosfomycin) for FY 2022. CONTEPO™ is an intravenously administered epoxide antibiotic intended for the treatment of complicated urinary tract infections (cUTI) including acute pyelonephritis (AP) caused by designated susceptible bacteria. Per the applicant, the drug inhibits cell wall synthesis at an earlier stage and provides new treatment for patients with cUTIs including acute pyelonephritis caused by *Escherichia coli* and *Klebsiella pneumonia* that have failed to respond to other first-line therapies.

CONTEPO™ is designated as a QIDP. The applicant initially applied for FDA approval when submitting a New Drug Application (NDA) in October 2018 seeking marketing approval of IV fosfomycin for injection (ZTI–01) for the treatment of patients 18 years and older with cUTI including acute pyelonephritis caused by designated susceptible bacteria. According to the applicant, on June 19, 2020, the FDA rejected the applicant's resubmitted NDA due to unresolved manufacturing issues that required an in-person inspection, which the FDA was not able to conduct due to travel restrictions. The applicant stated that it planned to resubmit an NDA after discussing next steps with the FDA and hoped to receive FDA approval prior to July 1, 2021.

The applicant previously applied for a new technology add-on payment for the same indication for FY 2021 and received conditional approval for new technology add-on payments for FY 2021, subject to CONTEPO™ receiving FDA marketing authorization before July 1, 2021 (85 FR 58724). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25391), we explained that if CONTEPO™ receives FDA marketing authorization before July 1, 2021, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. We stated that if the FDA marketing authorization is received on or after July 1, 2021, no new technology add-on payments will be made for cases involving the use of CONTEPO™ for FY 2021.

We further stated that if CONTEPO™ receives FDA marketing authorization before July 1, 2021, the applicant has indicated that it would withdraw its application for FY 2022 and would instead seek new technology add-on payments for CONTEPO™ for FY 2022 as a continuation of the conditional approval for FY 2021. The applicant requested in its application for FY 2022 that if the technology does not receive FDA marketing authorization by July 1, 2021, CMS conditionally approve CONTEPO™ for new technology add-on payments for FY 2022. We note that CONTEPO™ did not receive FDA marketing authorization by July 1, 2021.

The applicant applied for and received a unique ICD–10–PCS procedure code to identify cases involving the administration of CONTEPO™ in 2019. Effective October 1, 2019, CONTEPO™ administration can be identified by ICD–10–PCS procedure codes XW033K5 (Introduction of fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5) and XW043K5 (Introduction of fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5), which the applicant states are unique to CONTEPO™ administration.

With regard to the cost criterion, the applicant used the FY 2019 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving CONTEPO™ would most likely be mapped. According to the applicant, CONTEPO™ is anticipated to be indicated for the treatment of hospitalized patients who have been diagnosed with complicated urinary tract infections (cUTIs). The applicant identified 199 ICD–10–CM diagnosis code combinations that identify hospitalized patients who have been diagnosed with a cUTI. Searching the FY 2019 MedPAR data file for these ICD–10–CM diagnosis codes resulted in a total of 525,876 potential cases that span 507 unique MS–DRGs. The applicant noted that the cases identified are fewer than in the FY 2021 new technology add-on payment application. Per the applicant, this change occurred because the applicant excluded additional claims for Medicare Advantage and inpatient ''full-encounter'' claims from all cohorts. The applicant maintained that while cohorts are smaller, the effects on the results were minimal.

The applicant examined associated charges per MS–DRG and removed charges for potential antibiotics that may be replaced by the use of CONTEPO™. Specifically, the applicant identified 5 antibiotics currently used for the treatment of patients who have been diagnosed with a cUTI and calculated the cost of each of these drugs for administration over 14-day inpatient hospitalization. Because patients who have been diagnosed with a cUTI would typically only be treated with one of these antibiotics at a time, the applicant estimated an average of the 14-day cost for the 5 antibiotics. The applicant then converted the cost to charges by dividing the costs by the national average CCR of 0.187 for drugs from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). The applicant then standardized the charges for each case and inflated each case's charges by applying the FY 2021 IPPS/LTCH PPS final rule outlier charge inflation factor of 13.2 percent (85 FR 59039).

The applicant then added the charges for the new technology by calculating the per-day cost per patient. The applicant noted that the duration of therapy of up to 14 days (patients that had a cUTI with concurrent bacteremia) is consistent with the prospective prescribing information, and that it used this 14-day duration of therapy to calculate total inpatient cost. The applicant then converted these costs to charges by dividing the costs per patient by the national average cost-to charge ratio of 0.187 for drugs from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). The applicant calculated a final inflated case-weighted average standardized charge per case of $79,619 and a case weighted threshold of $59,237. Because the final inflated case-weighted average standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount, the applicant maintained it meets the cost criterion.

As summarized, the applicant used a 14-day duration of therapy to calculate total inpatient cost for purposes of its cost analysis. However, the applicant noted that the average number of days a patient would be administered CONTEPO™ will most likely fall between 10 to 14 days of therapy given the current guideline recommendations. Of these treatment days, the applicant noted that nearly all would occur during the inpatient hospital stay. Consistent with our historical practice, and as stated in the FY 2021 IPPS/LTCH PPS final rule, we believe the new technology add-on payment for CONTEPO™, if approved, would be based on the average cost of the technology and not the maximum (85 FR 58724). Without further information from the applicant regarding the average number of days CONTEPO™ is administered, we continue to believe using the middle ground of 12.5 days,

based on the 10–14 day period indicated by the applicant, is appropriate for this analysis to determine the average number of days CONTEPO™ is administered in the hospital. To assess whether the technology would meet the cost criterion using an average cost for the technology based on this 12.5-day period for CONTEPO™ administration, we converted the costs to charges by dividing the costs per patient by the national average cost-to charge ratio of 0.187 for drugs from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). Based on data from the applicant, this resulted in a final inflated average case-weighted standardized charge per case of $77,613, which exceeds the case weighted threshold of $59,237.

Because of the large number of cases included in this cost analysis, the applicant supplemented the analysis as described previously with additional sensitivity analyses. In these analyses, the previous cost analysis was repeated using only the top 75 percent of cases and the top 20 MS–DRGs. In these two additional sensitivity analyses, the final inflated case-weighted average standardized charge per case for CONTEPO™ of $70,718 and $70,046 exceeded the average case-weighted threshold amount of $55,388 and $55,468, respectively. Because the final inflated case-weighted average standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount, the applicant asserts that CONTEPO™ meets the cost criterion.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25391), we agreed with the applicant that CONTEPO™ (fosfomycin) meets the cost criterion. We stated that therefore, if CONTEPO™ does not receive FDA approval by July 1, 2021 to receive new technology add-on payments beginning with FY 2021, for FY 2022, per the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58739 through 58742), we proposed to conditionally approve CONTEPO™ for new technology add-on payments, subject to the technology receiving FDA marketing authorization by July 1, 2022 (that is, by July 1 of the fiscal year for which the applicant applied for new technology add-on payments (2022)). If CONTEPO™ receives FDA marketing authorization before July 1, 2022, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If the FDA marketing authorization is received on or after July 1, 2022, no new technology add-on payments would be made for cases involving the use of CONTEPO™ for FY 2022. As previously noted, the applicant has received a unique ICD–10–PCS procedure code to identify cases involving the administration of CONTEPO™. We stated that if CONTEPO™ receives FDA marketing authorization prior to July 1, 2021, we were proposing to continue making new technology add-on payments for CONTEPO™ in FY 2022.

As discussed previously, without further information from the applicant regarding the average number of days CONTEPO™ is administered, and consistent with our approach for the FY 2021 IPPS/LTCH PPS final rule, we believe using a 12.5-day duration of therapy is a reasonable approach for estimating the average cost of the technology. Based on preliminary information from the applicant at the time of the proposed rule, the cost of CONTEPO™ administered over 12.5 days is $3,500. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that if CONTEPO™ receives FDA marketing authorization prior to July 1, 2022, the maximum new technology add-on payment for a case involving the use of CONTEPO™ (fosfomycin) would be $2,625 for FY 2022 (that is, 75 percent of the average cost of the technology). Cases involving the use of CONTEPO™ that would be eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033K5 (Introduction of fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043K5 (Introduction of fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5).

We invited public comments on whether CONTEPO™ (fosfomycin) meets the cost criterion and our proposal to approve new technology add-on payments for CONTEPO™ (fosfomycin) for FY 2022.

Comment: A commenter, the applicant, supported CMS' proposal to approve new technology add-on payments for FY 2022 for CONTEPO™. The applicant also voiced support for CMS' proposal to grant conditional approval for new technology add-on payments for CONTEPO™ for FY 2022 in the event that it did not receive marketing approval by July 1, 2021, subject to CONTEPO™ receiving marketing approval by July 1, 2022. Per the applicant, in light of delays with FDA onsite inspections due to ongoing FDA travel restrictions, CONTEPO™ did not receive FDA approval by the July 1, 2021 deadline, and it will keep CMS informed with regard to the status of its NDA once a new PDUFA date is confirmed.

Response: We thank the applicant for their comment and update.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe CONTEPO™ meets the cost criterion. Therefore, because CONTEPO™ otherwise meets the new technology add-on payment criteria under the alternative pathway for products designated as QIDPs, we are granting a conditional approval for CONTEPO™ for new technology add-on payments, subject to the technology receiving FDA marketing authorization by July 1, 2022 (that is, by July 1 of the fiscal year for which the applicant applied for new technology add-on payments (2022)). If CONTEPO™ receives FDA marketing authorization before July 1, 2022, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If the FDA marketing authorization is received on or after July 1, 2022, no new technology add-on payments will be made for cases involving the use of CONTEPO™ for FY 2022.

Based on the information at the time of this final rule, the cost per case of CONTEPO™ is $3,500. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that, subject to CONTEPO receiving marketing authorization by July 1, 2022, the maximum new technology add-on payment for a case involving the use of CONTEPO™ will be for $2,625 for FY 2022 (that is 75 percent of the average cost of the technology). Cases involving the use of CONTEPO™ that would be eligible for new technology add-on payments will be identified by ICD–10–PCS codes: XW033K5 (Introduction of fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043K5 (Introduction of fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5).

(2) FETROJA® (cefiderocol)

Shionogi & Co., Ltd submitted an application for new technology-add on payments for FETROJA® (cefiderocol) for FY 2022. FETROJA® is an injectable siderophore cephalosporin indicated for the treatment of hospital-acquired bacterial pneumonia (HABP)/ventilator-associated bacterial pneumonia (VABP) on September 25, 2020. Per the applicant, FETROJA® should be used to treat infections where limited or no alternative treatment options are available and where FETROJA® (cefiderocol) is likely to be an appropriate treatment option, which may include use in patients with infections caused by documented or highly suspected carbapenem-resistant and/or multidrug-resistant gram-negative (GN) pathogens. The applicant asserts that the principal antibacterial/bactericidal activity of FETROJA® occurs with inhibiting GN bacterial cell wall synthesis by binding to penicillin-binding proteins.

FETROJA® was designated as a QIDP for HABP/VABP and received FDA marketing approval for this indication on September 25, 2020. FETROJA® became available on the market for the treatment of HABP/VABP after FDA approval for this indication. FETROJA® also has a QIDP designation and is FDA approved for cUTI, and was granted a new technology add-on payment under the alternative new technology add-on payment pathway for certain antimicrobials for this indication in the FY 2021 IPPS/LTCH final rule (85 FR 58721). The current new technology add-on payment application for FY 2022 is specific to the indication of HABP/VABP. According to the applicant, the ICD–10 Coordination and Maintenance Committee approved the following ICD–10–PCS codes to specifically describe the IV administration of FETROJA, effective October 1, 2020: XW033A6 (Introduction of cefiderocol anti-infective into peripheral vein, percutaneous approach, new technology group 6) and XW043A6 (Introduction of cefiderocol anti-infective into central vein, percutaneous approach, new technology group 6).

With regard to the cost criterion, the applicant conducted two analyses based on 100 percent and 75 percent of identified claims. For both scenarios, the applicant used the FY 2019 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for FETROJA® treatment would be mapped. The applicant identified eligible cases by searching the FY 2019 MedPAR for cases reporting ICD–10–CM codes for pneumonia and for resistance to antimicrobial drugs.

Under the first scenario of 100 percent of cases, the applicant identified 9,595 cases mapping to 203 MS–DRGs. Under the second scenario of 75 percent of cases, the applicant identified 7,218 cases mapping to 19 MS–DRGs. The applicant standardized the charges after calculating the average case-weighted unstandardized charge per case for both scenarios and removing 50 percent of charges associated with the drug revenue centers 025x, 026x, and 063x under both scenarios. Per the applicant, FETROJA® is expected to replace some of the drugs that would otherwise be utilized to treat these patients. The applicant stated that it believes 50 percent of these total charges to be a conservative estimate as other drugs will still be required for these patients during their hospital stay. The applicant then applied an inflation factor of 13.2 percent, which was the 2-year outlier charge inflation factor used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039), to update the charges from FY 2019 to FY 2021. The applicant then added charges for FETROJA® by dividing the total average hospital cost of FETROJA® by the national average cost-to-charge ratio (0.187) for drugs published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601).

The applicant calculated a final inflated case-weighted average standardized charge per case of $164,825 for the first scenario and $148,821 for the second scenario and an average case-weighted threshold amount of $78,296 for the first scenario and $73,607 for the second scenario. Because the final inflated case-weighted average standardized charge per case for each scenario exceeds the average case-weighted threshold amount for each scenario, the applicant asserted that the technology meets the cost criterion.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25392), we agreed with the applicant that FETROJA® (cefiderocol) meets the cost criterion and therefore proposed to approve FETROJA® for new technology add-on payments for FY 2022 when used for the treatment of HABP/VABP. Cases involving the use of FETROJA® that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033A6 or XW043A6.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of FETROJA® administered over an average of 10.4 days is $11,439.79. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of FETROJA® when used for the treatment of HABP/VABP would be $8,579.84 for FY 2022 (that is, 75 percent of the average cost of the technology).

We invited public comments on whether FETROJA® (cefiderocol) meets the cost criterion and our proposal to approve new technology add-on payments for FETROJA® for FY 2022 for the treatment of HABP/VABP.

Comment: A commenter, the applicant, supported CMS' proposal to approve new technology add-on payments for FY 2022 for FETROJA®. The applicant also noted two incorrect codes in the list of ICD–10–PCS codes for the administration of FETROJA in the proposed rule (86 FR 25392) and requested that we correct the list to include XW033A6 and XW043A6.

Response: We thank the applicant for its comment. We appreciate the clarification and note that in this final rule, as noted below, cases involving the use of FETROJA® eligible for new technology add-on payments will be identified by the ICD–10–PCS codes listed by the commenter.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe FETROJA® meets the cost criterion. Also, FETROJA® was designated as a QIDP for HABP/VABP and received FDA marketing approval for this indication on September 25, 2020. Therefore, we are finalizing our proposal to approve new technology add-on payments for FETROJA® for FY 2022. We consider the beginning of the newness period to commence on September 25, 2020 which is when the technology received FDA marketing authorization for this indication. Based on the information at the time of this final rule, the cost per case of FETROJA® is $11,439.79. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of FETROJA® for the HABP/VABP indication is $8,579.84 for FY 2022 (that

is 75 percent of the average cost of the technology). Cases involving the use of FETROJA® eligible for new technology add-on payments will be identified by ICD–10– PCS codes: XW033A6 (Introduction of cefiderocol anti-infective into peripheral vein, percutaneous approach, new technology group 6) or XW043A6 (Introduction of cefiderocol anti-infective into central vein, percutaneous approach, new technology group 6).

(3) RECARBRIO™ (imipenem, cilastatin, and relebactam)

Merck & Co. submitted an application for new technology add-on payments for RECARBRIO™ for FY 2022. RECARBRIO™ is a fixed-dose combination of imipenem, a penem antibacterial; cilastatin, a renal dehydropeptidase inhibitor; and relebactam, a novel b-lactamase inhibitor (BLI) administered via intravenous infusion. Per the applicant, RECARBRIO™ is indicated for the treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible Gram-negative bacteria. RECARBRIO™ is also indicated for complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI) and was approved for new technology add-on payment for these indications in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58728).

The applicant explained that the recommended dose of RECARBRIO™ is 1.25 grams administered by intravenous infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance (CrCl) 90 mL/min or greater. Per the applicant, the recommended treatment course suggests that a patient will receive 1 vial per dose and 4 doses per day. Per RECARBRIO™'s prescribing information, the recommended duration of treatment is 4 days to 14 days.

RECARBRIO™ is designated as a QIDP indicated for the treatment of HABP/VABP and received FDA approval through a supplemental NDA on June 4, 2020 for this indication. According to the applicant, RECARBRIO™ originally submitted an NDA for the cUTI and cIAI indications and received FDA approval on July 16, 2019. The applicant previously applied for the new technology add-on payment for the cUTI and cIAI indications, which CMS approved in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58728). The application for new technology add-on payments for FY 2022 is specific to the HABP and VABP indications. The applicant noted that RECARBRIO™ can be identified with ICD–10–PCS codes XW033U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into central vein, percutaneous approach, new technology group 5).

To demonstrate that the technology meets the cost criterion, the applicant searched the FY 2019 MedPAR Limited Data Set (LDS) for cases reporting ICD–10–CM diagnosis code J95.851 (Ventilator assisted pneumonia) for VABP, and the following list of codes for HABP:

Group	Code	Code Type	Description
Group 1	J181	ICD-10-CM Diagnosis Code	Lobar pneumonia, unspecified organism
Group 1	J150	ICD-10-CM Diagnosis Code	Pneumonia due to Klebsiella pneumoniae
Group 1	J151	ICD-10-CM Diagnosis Code	Pneumonia due to Pseudomonas
Group 1	J14	ICD-10-CM Diagnosis Code	Pneumonia due to Hemophilus influenzae
Group 1	J158	ICD-10-CM Diagnosis Code	Pneumonia due to other specified bacteria
Group 1	J155	ICD-10-CM Diagnosis Code	Pneumonia due to Escherichia coli
Group 1	J156	ICD-10-CM Diagnosis Code	Pneumonia due to other aerobic Gram-negative bacteria
Group 1	J158	ICD-10-CM Diagnosis Code	Pneumonia due to other specified bacteria
Group 1	J159	ICD-10-CM Diagnosis Code	Unspecified bacterial pneumonia
Group 1	J168	ICD-10-CM Diagnosis Code	Pneumonia due to other specified infectious organisms
Group 1	J17	ICD-10-CM Diagnosis Code	Pneumonia in diseases classified elsewhere
Group 1	J180	ICD-10-CM Diagnosis Code	Bronchopneumonia, unspecified organism
Group 1	J189	ICD-10-CM Diagnosis Code	Pneumonia, unspecified organism
Group 1	J9600	ICD-10-CM Diagnosis Code	Acute respiratory failure, unspecified whether with hypoxia or hypercapnia
Group 1	J9690	ICD-10-CM Diagnosis Code	Respiratory failure, unspecified, whether with hypoxia or hypercapnia
Group 1	J9620	ICD-10-CM Diagnosis Code	Acute and chronic respiratory failure

Additionally, for HABP, the applicant identified cases that included present on admission indicators of N (Diagnosis was not present at time of inpatient admission), U (Documentation insufficient to determine if condition was present at the time of inpatient admission), W (Clinically undetermined), or 1 (Unreported/not used).

The applicant identified a total 106,964 cases, which were mapped to 355 unique MS–DRGs. The applicant removed 88 MS–DRGs with minimal frequencies (fewer than 11 cases), leaving 106,655 cases mapping to 267 MS–DRGs. Per the applicant, the top 10 MS–DRGs covered approximately 34.1 percent of all patients. The applicant examined associated charges per MS–DRG and removed all pharmacy charges to be replaced using RECARBRIO™. The applicant then standardized and inflated the charges by applying the FY 2021 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.13218 (85 FR 59039).

The applicant estimated an average cost of RECARBRIO™ for the treatment of HABP and VABP in the inpatient setting based on the recommended dose of 1.25 grams (imipenem 500 mg, cilastatin 500 mg, relebactam 250 mg) administered by intravenous infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance (CLcr) 90 mL/min or greater. As stated previously, according to the applicant, the recommended treatment course suggests that a patient will receive 1 vial per dose, 4 doses per day within a recommended treatment duration of 4 to 14 days. To determine the cost per patient, the applicant stated it used the FY 2019 MedPAR analysis of total cases representing hospitalized patients who may be eligible for treatment involving RECARBRIO™ to identify a percentage of total cases per indication: HABP 94.07 percent of cases and VABP 5.93

percent. According to the applicant, it next identified the average length of stay per indication: HABP 14.2 days and VABP 24.2 days. The applicant also assumed that 70 percent of patients would receive RECARBRIO™ beginning on the fourth day after admission while the remaining 30 percent of these patients would receive RECARBRIO™ beginning on the second day of their hospitalization. The applicant then multiplied the daily dose cost by the two scenarios for each HABP and VABP indication to determine the cost per stay for each indication by days of drug use. Next it multiplied the cost per stay for each indication by the share of cases by days in use (70/30 percent split) to determine the weighted cost for days in use estimation. The applicant then summed the 70/30 percent case breakdown (weighted cost) for patients initiating on day 2 and 4 to determine the average cost per indication for HABP and VABP. Finally, the applicant multiplied the average cost per indication by the percent of total cases for HABP and VABP, then summed them to get the overall average cost. The applicant converted this cost to a charge by dividing the costs by the national average cost-to-charge ratio of 0.187 for drugs published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601) and added the resulting charges to determine the final inflated case-weighted average standardized charge per case.

The applicant calculated a final inflated case-weighted average standardized charge per case of $258,946 and an average case-weighted threshold amount of $123,172. The applicant also calculated an average case-weighted standardized charge per case for HABP and VABP separately using the same methodology previously described and determined final inflated case-weighted average standardized charges per case of $249,992 for HABP and $394,992 for VABP and average case-weighted thresholds of $117,466 for HABP and $214,869 for VABP.

In addition, because RECARBRIO™ was previously approved for a new technology add-on payment for the cUTI and cIAI indications, the applicant modified the added amount of the charge for RECARBRIO™ based on the cost calculation of the technology using all four indications. Using the same methodology previously described, the applicant determined final inflated case-weighted average standardized charges per case of $250,209 for HABP and VABP, $241,255 for HABP, and $386,255 for VABP and average case-weighted thresholds of $123,172 for HABP and VABP, $117,466 for HABP, and $214,869 for VABP. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount in each scenario, the applicant maintained that the technology met the cost criterion.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25394), we agreed with the applicant that RECARBRIO™ meets the cost criterion and therefore proposed to approve RECARBRIO™ for new technology add-on payments for FY 2022 when used for treatment of HABP and VABP. Based on preliminary information from the applicant at the time of the proposed rule, the cost of RECARBRIO™ is $12,768.68 when used for the treatment of HABP and VABP. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of RECARBRIO™ would be $9,576.51 for FY 2022 (that is, 75 percent of the average cost of the technology) when used for treatment of HABP and VABP.

We invited public comments on whether RECARBRIO™ (imipenem, cilastatin, and relebactam) meets the cost criterion and our proposal to approve new technology add-on payments for the RECARBRIO™ (imipenem, cilastatin, and relebactam) for the indications of HABP and VABP for FY 2022.

We did not receive any comments on our proposal to approve RECARBRIO™ for new technology add-on payments for FY 2022.

Based on the information provided in the application for new technology add-on payments, we believe RECARBRIO™ meets the cost criterion. Also, RECARBRIO™ is designated as a QIDP indicated for the treatment of HABP/VABP and received FDA approval through a supplemental NDA on June 4, 2020 for this indication. Therefore, we are finalizing our proposal to approve new technology add-on payments for RECARBRIO™ for FY 2022, and we consider the beginning of the newness period to commence on June 4, 2020 for the treatment of HABP/VABP, which is when the technology received FDA marketing authorization for this indication. Based on the information at the time of this final rule, the cost per case of RECARBRIO™ is $12,769. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the RECARBRIO™ for the treatment of HABP/VABP is $9,577 for FY 2022 (that is 75 percent of the average cost of the technology). Cases involving the use of RECARBRIO™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes: XW033U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into central vein, percutaneous approach, new technology group 5).

c. Other Comments

Comment: We received multiple comments regarding payment for QIDPs and new technology add-on payment policies, including that Medicare should pay QIDP antibiotics separately from DRGs, make payment for QIDP products at 100%, and reduce the new technology add-on payment approval timeframes to shorten application cycles to streamline access to coverage, coding, and payment for new technologies. Also, several commenters recommended CMS initiate accelerated antibacterial and antifungal guideline updates to facilitate clinician education and correspond with the new technology add-on payment pathway for antimicrobials. Another commenter recommended that CMS extend the new technology add- on payment pathway to microbiome therapeutics that also treat urgent antimicrobial threats, such as Clostridioides difficile infection (CDI). Similarly, several commenters recommended that CMS establish an additional new technology add-on payment pathway for Breakthrough and Regenerative Medicine Advanced Therapies (RMAT) designated products to enhance payment for these products that have received FDA marketing authorization and for Breakthrough gene therapy products, similar to the pathway developed for QIDPs. Furthermore, the commenters recommended the add-on payment amount for products that qualify for new technology add-on payment pathways should be similar to products qualifying for the QIDP and LPAD pathway which pursuant to § 412.88(a)(2)(ii)(B) is the lesser of: (1)

Seventy-five percent of the costs of the new medical service or technology; or (2) seventy-five percent of the amount by which the costs of the case exceed the standard DRG payment.

Response: We appreciate the commenters' recommendations for potential changes to the new technology add-on payment program and recognize the importance of addressing these critical issues. We will take these comments into consideration for future rulemaking.

Comment: A commenter stated that CMS should not extend the 20% adjustment codified in section 3710 of the CARES Act for discharges involving a patient diagnosed with COVID–19 beyond the duration of the PHE. A commenter recommended that CMS use its exceptions and adjustments authority under 42 U.S.C. 1886(d)(5)(I) to adopt a parallel policy that continues the 20 percent increase in the MS–DRG weight for discharges of patients diagnosed with COVID–19 through the end of the fiscal year in which the COVID–19 emergency period ends.

Response: Per the statute in section 3710 of the CARES Act, the 20% payment adjustment is scheduled to end at the end the PHE. Unless Congress extends the end date of the 20% payment adjustment beyond the end of the PHE, we expect to discontinue these payments at the time specified by the statute.

7. Comment Solicitation on the New Technology Add-On Payment Newness Period for Products Available Through an Emergency Use Authorization (EUA) for COVID–19

As noted previously, and explained in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights.

As we have discussed in prior rulemaking (77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market, when data reflecting the costs of the technology begin to become available for recalibration of the DRGs. In some specific circumstances, we have recognized a date later than FDA approval as the appropriate starting point for the 2-year to 3-year newness period for new technologies approved for add-on payments (85 FR 58734).

As discussed previously, in the FY 2009 IPPS final rule (73 FR 48561 through 48563), we revised our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. We stated that new technologies that have not received FDA approval do not meet the newness criterion. In addition, we stated we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective. For these reasons, we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also finalized at 42 CFR 412.87(c) (subsequently redesignated as 412.87(e)) that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances, licensures, and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to § 412.87(e)(2) to indicate that new technologies must receive FDA marketing authorization (for example, pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; approval of a New Drug Application (NDA); or Biologics License Application (BLA) licensure) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As noted in the FY 2021 IPPS/LTCH PPS final rule, this technical clarification did not change our longstanding policy for evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, and we continue to consider FDA marketing authorization as representing that a product has received FDA approval or clearance for purposes of eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

An EUA by the FDA allows a product to be used for emergency use, but under our longstanding policy, we believe it would not be considered an FDA marketing authorization for the purpose of new technology add-on payments, as a product that is available only through an EUA is not considered to have an FDA approval or clearance. Therefore, under the current regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible for new technology add-on payments.

Although an EUA is not an FDA approval or clearance that would be considered FDA marketing authorization within the meaning of § 412.87(e)(2), data reflecting the costs of products that have received an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance. CMS also recognizes that the manufacturers of products with EUAs (such as some COVID–19 treatments) might further engage with FDA to seek approval or clearance, and may be eligible for new technology add-on payments in the future. We sought comment on how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA.

Comment: We received multiple comments in response to our request for comment. Commenters recommended that CMS use the date of FDA approval, and not the date of the EUA, as the beginning of the 2-year to 3-year newness period. The commenters stated that a full FDA review process is in the interest of patient safety and clinical efficacy rather than expanding eligibility to include products under the expedited EUA process; and that data collected during the EUA period may reflect high variability in estimates of costs due to challenges associated with variable treatment practices in the context of the global pandemic and a novel disease. The commenters further stated that the data collected may not reflect government price subsidies provided for products during the EUA period. These factors may distort estimates of the cost of treatment and not appropriately reflect the total cost of care for patients who receive treatment using new COVID–19 therapeutics. A commenter also stated that while data

reflecting the costs of EUA products may become available from the date of the EUA, CMS should not base the newness period on data gathered during the EUA period, but rather, should monitor how pricing may have changed once the product receives full marketing authorization. Some commenters recommended that CMS allow EUAs as an appropriate form of FDA authorization as required under the new technology add-on payment process. A commenter stated that CMS' belief that an EUA should not be considered an FDA marketing authorization for the purpose of new technology add-on payments as a product that is available only through an EUA is not considered to have FDA approval or clearance, is highly problematic since an EUA is an authorization to allow products on the US market within the limitations established under the letter of authorization which contemplates marketing actions including advertising and promotional activities. The commenter further stated that it is clear from the text of the proposed rule that market authorization, not approval, is the criterion for add-on payment eligibility and that an EUA is a formal FDA authorization to market.

Response: We thank the commenters for their feedback and we will consider these comments for future rulemaking where applicable. With regard to the commenter who asserted that CMS should allow EUAs as an appropriate form of FDA authorization for new technology add-on payments as an EUA is a formal authorization to market, we note that there are distinct eligibility criteria for new technology add-on payments. As noted previously, historically, CMS has stated that for the purposes of new technology add-on payments, new technologies that have not received FDA approval do not meet the newness criterion. As noted in section F.1.a.3 of this final rule, in addition to the newness criterion, a technology must meet the substantial improvement criterion to qualify for new technology add-on payment. We have previously stated (73 FR 48561 through 48563) that we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective. For these reasons, we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. An EUA authorizes a product for emergency use when it is determined that it is reasonable to believe that a product is effective in treating a condition, and, when used under the conditions described in the EUA, the known and potential benefits outweigh the known and potential risks for the product.[755] As the safety and effectiveness of therapies under an EUA continue to be evaluated, [756] we are therefore unable to consider EUA as FDA marketing authorization for the purposes of new technology add-on payments.

8. Extension of the New COVID–19 Treatments Add-On Payment (NCTAP) Through the End of the FY in Which the PHE Ends

In response to the COVID–19 PHE, we established the New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71157–71158). We believe that as drugs and biological products become available and are authorized for emergency use or approved by FDA for the treatment of COVID–19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE. Therefore, effective for discharges occurring on or after November 2, 2020 and until the end of the PHE for COVID–19, we established the NCTAP to pay hospitals the lesser of: (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID–19.

We stated in the proposed rule that we anticipated that there might be inpatient cases of COVID–19, beyond the end of the PHE, for which payment based on the assigned MS–DRG may not adequately reflect the additional cost of new COVID–19 treatments. In order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE, we stated that we believed that the NCTAP should remain available for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends (for example, if the PHE were to end in FY 2022, until September 30, 2022).[757] At the same time, we stated that we also believed that any new technology add-on payments that may be approved for a COVID–19 treatment would also serve to mitigate any potential financial disincentives for hospitals to provide that new COVID–19 treatment, such that the NCTAP would no longer be needed for that same product. We noted that a COVID–19 treatment that is the subject of an application for FY 2022 new technology add-on payments and which receives FDA approval or clearance by July 1, 2021 would be eligible for consideration for new technology add-on payments for FY 2022.

Therefore, we proposed to extend the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends (for example, September 30, 2022). We also proposed to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for new technology add-on payments beginning FY 2022.

We stated that we believed the proposal to extend NCTAP for eligible products would allow some form of add-on payment (that is, NCTAP or new technology add-on payment) to continue uninterrupted for some period of time following the conclusion of the COVID–19 PHE, as we anticipated that there will continue to be inpatient cases of COVID–19 after the PHE ends. For example, if a drug or biological product with an EUA to treat COVID–19 does not receive FDA approval by July 1, 2021, and the PHE ends on December 31, 2021, the proposal would allow discharges involving that product to continue to be eligible for the NCTAP through September 30, 2022 (the end of FY 2022). We stated that if that same product receives FDA approval by July 1, 2022, it would be eligible for consideration of new technology add-on

[755] U.S. Food and Drug Administration. (2020, November 19). *Coronavirus (COVID–19) Update: FDA Authorizes Drug Combination for Treatment of COVID–19.* U.S. Food and Drug Administration. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-drug-combination-treatment-covid-19.*

[756] Ibid.

[757] On January 22, 2021, former Acting HHS Secretary Norris Cochran sent a letter to governors announcing that HHS has determined that the public health emergency will likely remain in place for the entirety of 2021, and when a decision is made to terminate the declaration or let it expire, HHS will provide states with 60 days' notice prior to termination.

payments beginning FY 2023, and new technology add-on payments, if approved, would begin on October 1, 2022 (the beginning of FY 2023).

We invited public comment on our proposals to continue the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends and to discontinue the NCTAP for products that are approved for new technology add-on payments.

Comment: Commenters overwhelmingly supported our proposal to continue the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends. Commenters stated that extending NCTAPs through the end of the fiscal year in which the PHE ends will enable providers to continue to treat COVID–19 patients without incurring excess losses.

Many commenters recommended that CMS remain flexible and consider further extending NCTAP to ensure the payment serves its intended purposes of supporting providers treating COVID–19 patients, even after the PHE, until such a time as the data used to establish payment for the applicable MS–DRGs reflects the cost of new COVID–19 treatments. A commenter specifically requested that if the PHE were to end less than three months prior to the end of the current fiscal year, CMS would allow NCTAP to continue for the remainder of the calendar year.

Some commenters supported our proposal to discontinue the NCTAP for products that are approved for new technology add-on payments beginning FY 2022. Another commenter recommended that CMS should not extend the NCTAP beyond its current expiration date for the existing treatments that had an opportunity to apply for new technology add-on payments. The commenter also stated that CMS should consider whether any treatments for which authorization is newly granted this calendar year should receive the NCTAP until the treatment may apply for and be granted new technology add-on payment status. The commenter asserted that CMS should evaluate safety, cost, and utilization data gathered since the NCTAP's inception to assess the financial impact and clinical outcomes of this policy to inform the decision on whether to grant new technology add-on payment status.

A commenter, the applicant for Veklury, supported paying NCTAP until it expires and then paying the new technology add-on payment once the NCTAP is no longer paid. The commenter provided the following table demonstrating that the NCTAP is more effective than a potential new technology add-on payment at mitigating the potential financial disincentives for a hospital to provide new COVID–19 treatments. The commenter identified relevant MS–DRGs using Veklury ICD–10 codes from FY 2020 MedPAR data and modeled estimated average payment rates using FY 2019 MedPAR data across a variety of scenarios.

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Payment Scenarios	Federal DRG Payment	New Technology Add-On Payment	New Technology Add-On Payment Percentage	Outlier Payment	Outlier Payment Percentage	Operating Outlier Threshold	NCTAP	NCTAP %	Total Payment
Baseline (regular DRG payment)	$16,901	$-	0%	$1,396	6%	$45,676	$-	0%	$18,297
Baseline + NTAP	$16,901	$1,305	73%	$1,315	6%	$46,981	$-	0%	$19,521
Baseline + NCTAP	$16,901	$-	0%	$1,396	6%	$45,676	$5,478	73%	$23,775
Baseline + 20% + NTAP	$20,281	$1,022	59%	$1,085	5%	$49,841	$-	0%	$22,389
Baseline + 20% + NCTAP	$20,281	$ -	0%	$1,150	5%	$48,819	$4,318	58%	$25,749

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The commenter stated that the NCTAP provides appropriate levels of support to reduce disincentives to use COVID–19 therapeutics, particularly when compared to new technology add-on payments. The commenter also stated that the NCTAP may be particularly useful to hospitals as a means to smooth the transition in payment once the 20% COVID–19 DRG add-on payment ends at the conclusion of the PHE, as mandated by the CARES Act. Therefore, the commenter suggested that instead of discontinuing the NCTAP when a new technology add-on payment is approved as we proposed, that CMS grant a conditional new technology add-on payment that would not take effect until the expiration of the NCTAP. They believed that this approach would be similar to the conditional new technology add-on payment established for certain antimicrobial products and would provide clear guidance for providers and more consistent access to NCTAP across COVID–19 treatment options. They suggested that once the NCTAP period has expired at the end of the fiscal year, the new technology add-on payment would immediately initiate and extend through the remainder of the new technology add-on payment's 2–3-year newness period, with the beginning of the newness period tied to the FDA approval date of the new technology and inclusive of the period where a conditional new technology add-on payment was in place and a product was eligible for NCTAP.

A commenter noted that in many instances, NCTAP would result in higher payment than the new technology add-on payment for the same product. The commenter recommended that CMS provide the add-on payment, either NCTAP or new technology add-on payment, whichever results in the highest total case-level Medicare payment for current NCTAP products that are approved for new technology add-on payment status. The commenter believes that this policy would encourage the use of these treatments and mitigate sudden declines in payment and should remain in effect through the fiscal year in which the PHE ends. Another commenter stated that it was concerned that for a product currently eligible for NCTAP that is approved for new technology add-on payment, Medicare payment may be inadequate if the NCTAP is discontinued, making it more difficult for providers to sustainably care for patients in the same manner as when the NCTAP was in place. The commenter encouraged CMS to consider allowing the payment structure for the NCTAP to continue even if a product has been approved for new technology add-on payments beginning in FY 2022.

A commenter recommended that CMS should consider NCTAP and new technology add-on payments to run consecutively and not concurrently so that these payment statuses do not overlap. Another commenter supported paying both NCTAP and new technology add-on payments for a single technology if the technology is eligible for both add on payments.

Response: We appreciate the commenters' feedback and support for the proposed extension of the NCTAP. After consideration of the comments received, and for the reasons discussed previously, we are finalizing our proposed extension of the NCTAP through the end of the fiscal year in which the PHE ends. We also appreciate the commenters' recommendations to further extend the NCTAP beyond this timeframe. Since we cannot predict the timing or circumstances around the end of the PHE, we will consider these for future rulemaking.

After consideration of the comments, we believe technologies eligible for new technology add-on payments should also be eligible for NCTAP. While we received some comments supporting our proposal to discontinue NCTAP for a product that is approved for new technology add-on payments, we agree with the other commenters that the NCTAP is more effective than a potential new technology add-on payment at mitigating the potential financial disincentives for a hospital to provide new COVID–19 treatments. By making an NCTAP for technologies also eligible for new technology add-on payment, we believe this will mitigate any financial disincentives for treatments for COVID–19 depending on whether the treatment is eligible for new technology add-on payment or NCTAP only. Specifically, as demonstrated by the commenter above, the NCTAP without new technology add-on payment can result in a higher add-on payment than the new technology add-on payment without NCTAP. We do not believe technologies approved for new technology add-on payment should be disadvantaged and receive a lower add-on payment than those technologies eligible for NCTAP. Allowing for both NCTAP and new technology add-on payments for technologies eligible to receive both will result in the products receiving an equivalent payment in the amount of the NCTAP.

Therefore, after review of the comments received, we are not finalizing our proposal to discontinue NCTAP for discharges on or after October 1, 2021 for a product that is approved for new technology add-on payments beginning FY 2022, but are instead finalizing to extend NCTAP through the end of the FY in which the PHE ends for all eligible products, including those approved for new technology add-on payments for FY 2022. However, we are also finalizing that we will reduce the NCTAP for an eligible case by the amount of any new technology add-on payments so that we do not create a financial disincentive between technologies eligible for both the new technology add-on payment and NCTAP compared to technologies eligible for NCTAP only. This will ensure that the add-on payment for a technology eligible for both new technology add-on payments and NCTAP is equivalent to that of a technology only eligible for the NCTAP.

As discussed in section F.5.t., we are approving Veklury for FY 2022 new technology add on payments. Veklury is the only COVID–19 treatment eligible for new technology add-on payments in FY 2022. Therefore, cases involving the use of Veklury in FY 2022 are eligible for both new technology add-on payments and NCTAP, with any new technology add-on payment reducing the amount of any NCTAP for the same treatment. Accordingly, cases of Veklury will receive a total add-on payment that will be equal to the payment it would receive if it were only eligible for NCTAP.

As discussed above, we are finalizing our proposal to extend the NCTAP for eligible products through the end of the fiscal year in which the PHE ends, with modifications. Specifically, we are finalizing to extend the NCTAP through the end of the fiscal year in which the PHE ends for all eligible products, including those approved for new technology add-on payments for FY 2022. We are not finalizing our proposal to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for new technology add-on payments beginning FY 2022. Instead, we are finalizing that we will continue to allow NCTAP for cases eligible for the new technology add-on payment, through the end of the fiscal year in which the PHE ends, with the new technology add-on payment reducing the amount of the NCTAP, as discussed previously.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2022 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this final rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050, which expires on March 31, 2022.) This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for FY 2022 is discussed in section II.B. of the Addendum to this final rule.

As discussed in section III.I. of the preamble of this final rule, we also take into account the geographic reclassification of hospitals in

accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2022 is discussed in section II.A.4.b. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are applying to the FY 2022 wage index appears under sections III.E. and F. of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) for the FY 2022 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963 and 49973 through 49982)) for a full discussion of our implementation of the OMB statistical area delineations beginning with the FY 2015 wage index. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2016, beginning with the FY 2017 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2017 IPPS/LTCH PPS final rule. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we continued to use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2018, beginning with the FY 2019 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 17–01, we refer readers to the FY 2019 IPPS/LTCH PPS final rule. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300 through 42301), we continued to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01.

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. Historically OMB bulletins issued between decennial censuses have only contained minor modifications to CBSA delineations based on changes in population counts. However, *OMB's 2010 Standards for Delineating Metropolitan and Micropolitan Standards* created a larger mid-decade redelineation that takes into account commuting data from the American Commuting Survey. As a result, the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) we adopted the updates set forth in OMB Bulletin No. 18–04 effective October 1, 2020, beginning with the FY 2021 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 18–04, we refer readers to the FY 2021 IPPS/LTCH PPS final rule.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20–01.pdf*). In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area, one new component of an existing Combined Statistical Area and changes to New England City and Town Area (NECTA) delineations. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58744), we stated that if appropriate, we would propose any necessary wage area updates based on OMB Bulletin No. 20–01 in the FY 2022 IPPS/LTCH PPS proposed rule. After reviewing OMB Bulletin No. 20–01, we have determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare wage index for FY 2022. Specifically, the updates consisted of changes to NECTA delineations and the creation of a new Micropolitan Statistical Area which was then added as a new component to an existing Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in FY 2021 IPPS/

LTCH PPS final rule (85 FR 58746), we include hospitals located in Micropolitan Statistical areas in each State's rural wage index. Therefore, while we are adopting the updates set forth in OMB Bulletin No. 20–01 consistent with our general policy of adopting OMB delineation updates, we note that specific wage index updates would not be necessary for FY 2022 as a result of adopting these OMB updates. In other words, these OMB updates would not affect any hospital's geographic area for purposes of the wage index calculation for FY 2022.

For FY 2022, we are continuing to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01, 17–01, 18–04 and 20–01, although as noted above the latter Bulletin did not require any wage area updates.

We note that, in connection with our adoption in FY 2021 of the updates in OMB Bulletin 18–04, we adopted a policy to place a 5 percent cap, for FY 2021, on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition is set to expire at the end of FY 2021. However, given the unprecedented nature of the ongoing COVID–19 public health emergency (PHE), we also sought comment on whether it would be appropriate to continue to apply a transition to the FY 2022 wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04. For example, such an extended transition could potentially take the form of holding the FY 2022 wage index for those hospitals harmless from any reduction relative to their FY 2021 wage index. If we were to apply a transition to the FY 2022 wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04, we also sought comment on making this transition budget neutral, as is our usual practice, in the same manner that the FY 2021 transition was made budget neutral as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58755).

Comment: We received several comments strongly recommending CMS extend a transition policy similar to that implemented in FY 2020 and FY 2021. Several commenters, citing the severity and continuing impact of changes related to the OMB updates, the low wage index policy, and the lingering financial burden caused by the COVID–19 PHE, urged CMS to add an additional year of transition, applied in a budget neutral manner. These commenters stated that given the wide-ranging factors impacting wage index values, it would not be equitable to limit the transition adjustment only to the effects of the revised labor market delineations. The commenters requested the transition be implemented more broadly to all hospitals experiencing large declines in wage index values. Many of these commenters recommended CMS consider making a permanent 5 percent maximum reduction policy to protect hospitals from large year-to-year variations in wage index values as a means to reduce overall volatility.

Other commenters requested that CMS extend a hold harmless policy for all hospitals negatively affected by CMS' adoption of revised delineations until OMB releases further revisions predicated on the results of the 2020 decennial census. A commenter recommended a hold-harmless transition be applied specifically to hospitals in CBSAs that were negatively affected by the FY 2021 adoption of revised CBSAs, citing specific CBSAs they believed warranted an additional transition adjustment.

Several commenters, while supporting some form of transition adjustment for negatively affected hospitals, requested any such adjustment be made in a non-budget neutral manner. These commenters expressed their preference that any such adjustment should not come at the expense of the providers themselves. Some commenters stated that such a budget neutrality adjustment would disadvantage providers who have increased their wage index values due to a variety of factors.

Response: After consideration of the comments, we are applying an extended transition to the FY 2022 wage index for hospitals. Specifically, for hospitals that received the transition in FY 2021, we are continuing a wage index transition for FY 2022 under which we will apply a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 to mitigate significant negative impacts of, and provide additional time for hospitals to adapt to, the CMS decision to adopt the revised OMB delineations. Also, as discussed in the FY 2021 IPPS/LTCH final rule, we believe applying a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year is an appropriate transition as it provides predictability in payment levels from FY 2021 to the upcoming FY 2022 as well as effectively mitigating any significant decreases in the wage index for FY 2022.

We considered comments requesting that we apply the transition adjustment in FY 2022 to all hospitals with significant reductions in wage index values (not just those that received the transition adjustment in FY 2021). Specifically, the policy commenters recommended would extend not only to specific changes in wage index policy (such as the introduction of the low wage policy or CMS's adoption of revised OMB labor market delineations), but would address any significant reductions in hospitals' wage index values, including changes in hospital average hourly wage values and changes in various reclassification statuses. We also considered comments recommending a 5-percent cap become a permanent policy for future fiscal years. We considered how best to address these potential scenarios in a consistent and thoughtful manner, and we reiterate that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as any approaches to addressing any significant effects on Medicare payments resulting from these potential scenarios, in notice and comment rulemaking. In FY 2020 and FY 2021, CMS implemented two separate transition policies limiting any hospital to a 5 percent year-to-year reduction in wage index values. In FY 2020, the purpose of the transition was to address potential impacts due to implementation of the low wage policy. In FY 2021, the purpose was to address the impact of CMS's adoption of the revised OMB labor market delineations. Both the low wage policy and the adoption of revised OMB delineations had wide ranging wage index implications; some of which could not be readily isolated in order to target the negative impacts, such as individual hospital reclassification considerations. CMS determined it would be appropriate to apply the transition to all hospitals experiencing significant reductions in wage index values. There is no specific wage index policy finalized in FY 2022 that warrants a similar application of a transition cap to all hospitals. For FY 2022, we are limiting the transition policy only to hospitals that received a transition adjustment in FY 2021 in order to

provide additional time for these hospitals to adapt to the FY 2021 changes.

We considered the comments recommending we not apply this continued transition in a budget neutral manner. We believe limiting the transition in FY 2022 to a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 rather than holding the hospital's FY 2022 wage index harmless from any reduction relative to its FY 2021 wage index balances the commenters' concerns by limiting the impact of the budget neutrality factor applied to the standardized amount while mitigating any continued significant decreases in the wage index for FY 2022. Therefore, for FY 2022, similar to FY 2021, we are applying a budget neutrality adjustment to the standardized amount so that our transition, as previously described, is implemented in a budget neutral manner under our authority in section 1886(d)(5)(I) of the Act. Implementing the transition wage index in a budget neutral manner is consistent with past practice (for example, 79 FR 50372 and 84 FR 42338) where CMS has used its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to budget neutralize transition wage index policies when such policies allow for the application of a transitional wage index only when it benefits the hospital. We believe, and continue to believe, that it would be appropriate to ensure that such policies do not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied these transition policies (79 FR 50372 and 84 FR 42337 through 42338).

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. We believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2020. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html*. We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to discontinue the use of the SSA county codes and began using only the FIPS county codes for purposes of cross walking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates, which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule.

For FY 2022, we are continuing to use only the FIPS county codes for purposes of cross walking counties to CBSAs. For FY 2022, Tables 2 and 3 associated with this final rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the latest FIPS code updates.

B. Worksheet S–3 Wage Data for the FY 2022 Wage Index

The FY 2022 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2018 (the FY 2021 wage indexes were based on data from cost reporting periods beginning during FY 2017).

1. Included Categories of Costs

The FY 2022 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);
- Home office costs and hours;
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)); and
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2021, the wage index for FY 2022 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2022 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

We did not receive any comments on the discussion in this section.

C. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2022 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10, OMB Control Number 0938–0050 with expiration date March 31, 2022) for cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018. For wage index purposes, we refer to cost reports during this period as the ''FY 2018 cost report,'' the ''FY 2018 wage data,'' or the ''FY 2018 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the FY 2022 wage index includes FY 2018 data submitted to us as of the end of June 2021. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We suggested our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2022 wage index, we identified and excluded 86 providers with aberrant data that should not be included in the wage index. However, we stated that if data elements for some of these providers are corrected, we intended to include data from those providers in the final FY 2022 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 19, 2021. For the final FY 2022 wage index, we restored 28 hospitals to the wage index because their data was either verified or improved, but we also removed the data of 5 hospital for the first time after the proposed rule due to its data being aberrant or due to conversion to CAH status. Thus, 63 hospitals with aberrant data remain excluded from the FY 2022 wage index (86 − 28 + 5 = 63).

In constructing the proposed FY 2022 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2018, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We stated in the proposed rule (86 FR 25398) that we believe including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index.

For the proposed FY 2022 wage index, we removed 3 hospitals that converted to CAH status on or after January 24, 2020, the cut-off date for CAH exclusion from the FY 2021 wage index, and through and including January 24, 2021, the cut-off date for CAH exclusion from the FY 2022 wage index. Since the proposed rule, we learned of 2 more hospital that converted to CAH status on or after January 24, 2020, and through and including January 24, 2021, the cut-off date for CAH exclusion from the FY 2022 wage index, for a total of 5 hospitals that were removed from the FY 2022 wage index due to conversion to CAH status. In summary, we calculated the FY 2022 wage index using the Worksheet S–3, Parts II and III wage data of 3,182 hospitals.

For the FY 2022 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the FY 2022 wage index associated with this final rule (available via the internet on the CMS website), includes separate wage data for the campuses of 21 multicampus hospitals. The following chart lists the multicampus hospitals by CSA certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

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Multicampus Hospitals by CSA CCN and FTE Percentages			
Main Campus Provider Number	Main Campus Full-Time Equivalent (FTE) Percentage	Sub Campus Provider Number	Sub Campus Full-Time Equivalent (FTE) Percentage
050121	0.85	05B121	0.15
070022	0.99	07B022	0.01
070033	0.93	07B033	0.07
100029	0.55	10B029	0.45
100167	0.55	10B167	0.45
140010	0.82	14B010	0.18
220074	0.89	22B074	0.11
330103	0.63	33B103	0.37
330195	0.89	33B195	0.11
330214	0.96	33B214	0.04
330234	0.75	33B234	0.25
340115	0.95	34B115	0.05
360020	0.97	36B020	0.03
390006	0.94	39B006	0.06
390115	0.86	39B115	0.14
390142	0.83	39B142	0.17
450330	0.98	45B330	0.02
460051	0.81	46B051	0.19
510022	0.94	51B022	0.06
520009	0.71	52B009	0.29
670062	0.66	67B062	0.34

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We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other, variable, digits in the CCN.

Comment: Several commenters strongly opposed the exclusion of hospitals' wage data. These commenters stated that excluding accurate and verified data is inconsistent with the extensive process established by CMS to ensure the accuracy and reliability of hospital wage index data.

A commenter stated that several of the 86 hospitals CMS identifies as having ''aberrant'' data are California hospitals whose wages are higher than their core-based statistical average (CBSA) average. The commenter stated that in the proposed rule CMS does not cite specific reasons why the agency believes the data from these hospitals are ''aberrant.'' Therefore, the commenter stated that the excluded hospitals and other stakeholders are left to infer that CMS is excluding these hospitals because their wages are higher than those of other hospitals in the CBSA. The commenter explained that in the absence of explanation from the agency, stakeholders are left to make educated guesses as to why CMS has deemed the wage data aberrant, limiting their ability to fully comment on the exclusion of individual hospitals. The commenter alleged that CMS is using arbitrary and undisclosed criteria to exclude these hospitals.

The commenter continued that the FFY 2022 wage data from worksheet S–3 of cost reports filed during FFY 2018 for the excluded hospitals with average hourly wages that are higher than the CBSA average have been reviewed by CMS and its MAC as part of the well-established Medicare wage index review process (just like all other hospitals). The commenter indicated that, in accordance with the wage index review process, as defined in CMS' Wage Index Development Timetable, at least one of the hospitals in question submitted corrected data in a timely manner that was reviewed and accepted by the MAC. The commenter stated that, in accordance with Medicare's wage index review process, the excluded hospitals' FFY 2018 worksheet S–3 wage data

were determined by the MAC to be accurate.

Commenters specifically raised the following concerns about lawfulness of excluding wage data for these hospitals: Section 1395ww(d)(3)(E) of the statute does not provide the authority for CMS to delete accurately-reported wage data; excluding hospitals without any definable standards is an abuse of discretion, creates uncertainty, and is arbitrary and capricious; the proposed exclusion is procedurally improper without notice-and-comment rulemaking in accordance with the Administrative Procedure Act (APA); excluding accurate wage data disregards labor costs and improperly substitutes CMS' judgment of reasonable wage levels for actual, free-market wage data; and singling out a health system due to its collective bargaining practices undermines the National Labor Relations Act (NLRA).

Several commenters stated that high labor costs are a true reflection of the challenging labor markets in California and the fact that wages are influenced by labor negotiations does not render them any less valid.

Commenters also expressed concern regarding the effects of excluding the hospitals' wage data. A few commenters stated that excluding the wage data for the hospitals will decrease payments to hospitals in those CBSAs significantly, jeopardizing access to care for Medicare beneficiaries across California. Many commenters stated that excluding the hospitals' wage data will also harm inpatient psychiatric facilities, inpatient rehabilitation facilities, skilled nursing facilities, and other provider types whose payments are impacted by the wage index, and noted that CMS did not identify the fiscal impacts of the exclusions in its respective regulatory impact analyses for the IPF, IRF, SNF, and the IPPS proposed rules.

Response: We received similar comments in FY 2016 and reiterate the points we made in the FY 2016 IPPS/LTCH final rule (80 FR 49490–49491).

Section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We believe that, under this section of the Act, we have discretion to exclude aberrant hospital data from the wage index PUFs to help ensure that the costs attributable to wages and wage-related costs in fact reflect the relative hospital wage level in the hospitals' geographic area.

Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. Hospitals are aware that both the MACs (via instructions issued by CMS) and CMS evaluate the accuracy and reasonableness of hospitals' wage index data, and hospitals may appeal to CMS as part of the April and June appeals processes. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that the MACs and, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. Each year in the IPPS/LTCH PPS proposed rule, we discuss the process wherein CMS suggested the MACs to ''revise or verify data elements that result in specific edit failures'' (86 FR 25398). In the FY 2022 IPPS/LTCH PPS proposed rule, similar to the proposed rules of prior years, we stated that we included the wage data for facilities that were IPPS hospitals in FY 2012, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is appropriate, in general, to reflect the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages (80 FR 24464). That is, a hospital is included in the wage index if its data are reasonable, regardless of whether the hospital is open or whether it has terminated after the relevant past period, because the wage index is constructed to represent the relative average hourly wage for each labor market area in that past period. Thus, reasonableness and relativity to each area's average hourly wages have been longstanding tenets of the wage index development process that CMS has articulated in rulemaking.

We disagree with the commenters that removing hospitals from the FY 2022 wage index PUFs was arbitrary and undermined the MAC desk review process because, as discussed above, as a standard part of the refinement of the annual wage index, CMS evaluates the wage data for both accuracy and reasonableness to ensure that the wage index is a relative measure of the labor value provided to a typical hospital in a particular labor market area. As part of this evaluation process, it is CMS, not the MACs, that makes the decisions to include or exclude a hospital's data from the wage index, and it would not be appropriate for CMS to make such decisions prior to a desk review being performed. The commenters seem to indicate that only hospitals with high average hourly wages were removed from the PUFs. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25398), we stated that ''For the proposed FY 2022 wage index, we identified and excluded 86 providers with aberrant data that should not be included in the wage index. If data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2022 wage index''. We note that we never anticipated that the data of all 86 hospitals would be corrected; we only anticipated that the data of some of those hospitals would be corrected. This is because approximately 42 hospitals were deleted from the FY 2022 proposed wage index for reasons that would make their data unresolvable, including, but not limited to, termination (during or since the relevant past period), low/no Medicare utilization, being a CAH, or not reporting any wage data. Thus, ''aberrant'' hospitals are not limited to only hospitals that fail edits for reasonableness, but also include hospitals whose data are unresolvable. In fact, the number of hospitals deleted from the January or April 2021 PUFs due to having an extraordinarily high average hourly wage (and no other significant edit failures) was a small percentage of the 86 excluded hospitals (11.6 percent). Approximately 45 hospitals excluded from the January 2022 PUF had the potential to improve their data and be included in the April 2015 PUF and/or the final rule wage index. As we stated earlier, we received corrected data or improved documentation for 28 hospitals. Therefore, we are including these 28 hospitals in the final FY 2022 wage index. This demonstrates the effectiveness of our process—hospitals were included in final wage index because these hospitals were responsive to the MACs' and CMS' requests for sufficient documentation to improve their data. Consequently, the majority of hospitals whose data were excluded from the proposed wage index but had the potential to improve their data are included in the FY 2022 final wage index. We believe the final wage index is all the more accurate as a result.

Regarding the hospitals in California to which a commenter referred, without knowing the specific provider numbers we are left to assume which providers the commenter is referring to. In any case, we use the following example of

a hospital in California removed from the FY 2022 wage index. The hospital is located in CBSA 23420 (Fresno, California) and had a very high average hourly wage and was removed from the wage data even though the hospital's wage data was properly documented. However, the hospital does not merely have the highest average hourly wage in the CBSA; its average hourly wage is extremely and unusually high, significantly higher than the next highest average hourly wage in that CBSA and in the surrounding areas. While we believe this is a result of the unique salary structure and business model of the hospital's owner, not from a lack of reliability in its wage data, we believe the data is nonetheless aberrant and we therefore have authority to remove it. We do not believe that the average hourly wage of this particular hospital accurately reflects the economic conditions in its labor market area during the FY 2018 cost reporting period. Therefore, its inclusion in the wage index would not ensure that the FY 2022 wage index represents the labor market area's current wages as compared to the national average of wages. Rather, its inclusion would distort the average hourly wage of its labor market area. Accordingly, we have exercised our discretion to remove this hospital's wage data from the FY 2022 wage index.

Furthermore, just as CMS has excluded certain hospitals from the wage index with extraordinarily high average hourly wages relative to their labor market areas, CMS also has excluded hospitals with extraordinarily low average hourly wages relative to their labor market areas. An objective comparison of the hospitals included in the FY 2022 preliminary PUF to the hospitals included in the January and April 2022 PUFs demonstrates CMS' ''fairness'' in evaluating the appropriateness and relativity of the wage data of hospitals with both extraordinarily low and extraordinarily high average hourly wages. While some hospitals with high extraordinarily high average hourly wages remain excluded from the FY 2022 final wage index, some hospitals with extraordinarily low average hourly wages also remain excluded from the FY 2022 final wage index. Therefore, we disagree with commenters' assertions that we have been ''arbitrary and capricious'' and have ''abused'' our discretion in excluding hospitals from the wage index.

We also note that each time a PUF is posted, CMS instructs the MACs to send letters to each of their hospitals notifying and instructing them to review their wage index data that were just posted. Hospitals that review each PUF and observe that they are excluded may then submit an April appeal to CMS, and/or contact CMS and the MAC to discuss possible ways to revise or verify their data for inclusion in the wage index. We believe the established annual wage index timetable grants sufficient time for hospitals to review, appeal, and/or correct their data. We also welcome State hospital associations to be more proactive in the process of urging their constituents to be responsive to the MACs' and CMS' requests for documentation and to become more involved in resolving issues related to aberrant data. We note that it has never been CMS' policy to disclose audit protocol. However, we may consider a limited proposal regarding criteria for excluding a hospital's data from the wage index due to its overall average hourly wage being either too high or too low, as well as utilizing additional methods of communicating with stakeholders regarding the adequacy of their wage data.

Finally, we provide an impact of the overall impact of the wage index with regard to the IPPS. We do not provide an impact for each hospital excluded from the wage data. The cost report data of the providers deleted from the wage index is provided with each public use file and commenters can conduct an analysis of any change to the wage index if we were to restore the data of a hospital deleted from the wage index. With regard to the other PPSs, we refer commenters to the rulemaking of those PPSs for comments on the wage index and any impact analysis.

Comment: Commenters expressed concern that the wage data collected during the PHE will be less reflective of regional wages. Commenters suggest CMS consider not using the 2020 and 2021 data to set future wage indices. A few commenters stated that additional responsibilities on hospital staff that were also due September 2020, such as the triennial Occupational Mix Survey, created opportunities for errors into the FY 2022 wage indexes.

Response: FY 2022 uses wage data from 2018 which is not affected by the COVID–19 PHE. FYs 2023, 2024 and 2025 would typically use wage data from 2020 and 2021 since the wage index is on a four-year lag with regard to the data. We will consider comments on the 2020 and 2021 wage data in future rulemaking, as applicable.

D. Method for Computing the FY 2022 Unadjusted Wage Index

As we stated in the proposed rule (86 FR 25400), the method used to compute the FY 2022 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2021 IPPS/LTCH PPS final rule (see 85 FR 58758 through 58761, September 18, 2020), and we did not propose any changes to this methodology. We have restated our methodology in this section of this rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the wage index (in this case, for FY 2022, these were data from cost reports for cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018). In addition, we included data from some hospitals that had cost reporting periods beginning before October 2017 and reported a cost reporting period covering all of FY 2018. These data were included because no other data from these hospitals would be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2018 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2018 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows

directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4. The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43). We then compute the amounts of overhead salaries and hours to be allocated to the excluded areas by multiplying, the previously discussed ratio, by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to the excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following: (Lines 26 through 43 − Lines 28, 33 and 35)/ ((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).
- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.
- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2017 through April 15, 2019, for private industry hospital workers from the BLS' Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose to make any changes to the usage of the ECI for FY 2022. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSA's wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306) August 16, 2019). We stated that we believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the FY 2022 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website) which contains the area wage indexes, we include a footnote to indicate to which CBSAs this policy applies. These CBSAs' wage indexes would be equal to total urban salaries plus wage-related costs (from Step 5) in the respective State, divided by the total urban hours (from Step 4) in the respective State, divided by the national average hourly wage (from Step 8) (see 84 FR 42305 and 42306) August 16, 2019). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded, as discussed in this section of this rule.

We refer readers to section II. of the Appendix of the final rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI. of the Addendum to the final rule and available via the internet on the CMS website.

Following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306; August 16, 2019). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2017, through April 15, 2019, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose any changes to the usage of the ECI for FY 2022. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

Wage Index Adjustment Factors		
Midpoint of Cost Reporting Period After	**Midpoint of Cost Reporting Period Before**	**Adjustment Factor**
10/14/2017	11/15/2017	1.03317
11/14/2017	12/15/2017	1.03154
12/14/2017	01/15/2017	1.02988
01/14/2018	02/15/2018	1.02816
02/14/2018	03/15/2018	1.02638
03/14/2018	04/15/2018	1.02447
04/14/2018	05/15/2018	1.02238
05/14/2018	06/15/2018	1.02011
06/14/2018	07/15/2018	1.01780
07/14/2018	08/15/2018	1.01560
08/14/2018	09/15/2018	1.01350
09/14/2018	10/15/2018	1.01140
10/14/2018	11/15/2018	1.00920
11/14/2018	12/15/2018	1.00690
12/14/2018	01/15/2019	1.00456
01/14/2019	02/15/2019	1.00226
02/14/2019	03/15/2019	1.00000
03/14/2019	04/15/2019	0.99781

For example, the midpoint of a cost reporting period beginning January 1, 2018, and ending December 31, 2018, is June 30, 2018. An adjustment factor of 1.01780 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2017, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2022, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the methodology, as previously discussed, we stated in the proposed rule (86 FR 25402) that the proposed FY 2022 unadjusted national average hourly wage was $46.42.

We did not receive any comments regarding the discussion of our method for computing the FY 2022 unadjusted wage index. Based on the previously described methodology, the final FY 2022 unadjusted national average hourly wage is the following:

Final FY 2022 Unadjusted National Average Hourly Wage	$46.52

E. Occupational Mix Adjustment to the FY 2022 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather

than geographic differences in the costs of labor.

1. Use of 2019 Medicare Wage Index Occupational Mix Survey for the FY 2022 Wage Index

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19903) and final rule (82 FR 38137), we collected data in 2016 to compute the occupational mix adjustment for the FY 2019, FY 2020, and FY 2021 wage indexes. A new measurement of occupational mix is required for FY 2022.

The FY 2022 occupational mix adjustment is based on a new calendar year (CY) 2019 survey. Hospitals were required to submit their completed 2019 surveys (Form CMS–10079, OMB number 0938–0907, expiration date September 31, 2022) to their MACs by September 3, 2020. The preliminary, unaudited CY 2019 survey data were posted on the CMS website on September 8, 2020. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2022 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Calculation of the Occupational Mix Adjustment for FY 2022

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25403), for FY 2022, we proposed to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2022 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this final rule (which is available via the internet on the CMS website), which contains the final FY 2022 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this final rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2022 wage index. For the proposed FY 2022 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,159 hospitals, and we used the occupational mix surveys of 2,955 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 94 percent (2,955/3,159). For the proposed FY 2022 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2022 occupational mix adjusted national average hourly wage was $46.37.

We did not receive any comments on our proposed calculation of the occupational mix adjustment to the FY 2022 wage index. Thus, for the reasons discussed in this final rule and in the FY 2022 IPPS/LTCH PPS proposed rule, we are finalizing our proposal, without modification to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index and to apply the occupational mix adjustment to 100 percent of the FY 2022 wage index.

For the final FY 2022 wage index, we are using the Worksheet S3, Parts II and III wage data of 3,182 hospitals, and we are using the occupational mix surveys of 3,028 hospitals for which we also have Worksheet S–3 wage data, which is a ''response'' rate of 95 percent (3,028/3,182). For the final FY 2022 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the final FY 2022 occupational mix adjusted national average hourly wage is the following:

Final FY 2022 Occupational Mix Adjusted National Average Hourly Wage	$46.47

F. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2022 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this final rule, for FY 2022, we are applying the occupational mix adjustment to 100 percent of the FY 2022 wage index. We calculated the occupational mix adjustment using data from the 2019 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

The FY 2022 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$44.45
National LPN and Surgical Technician	$26.83
National Nurse Aide, Orderly, and Attendant	$18.53
National Medical Assistant	$19.50
National Nurse Category	$37.42

The national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2019 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) the following:

National Percentage of Hospital Employees in the Nurse Category	**42%**
National Percentage of Hospital Employees in the All Other Occupations Category	58%
Range of Percentage of Hospital Employees in the Nurse Category (CBSA Level)	Low of 20 Percent in one CBSA to a high of 66 percent in another CBSA

We compared the FY 2022 occupational mix adjusted wage indexes for each CBSA to the unadjusted wage indexes for each CBSA. Applying the occupational mix adjustment to the wage data resulted in the following:

Comparison of the FY 2022 Occupational Mix Adjusted Wage Indexes to the Unadjusted Wage Indexes by CBSA	
Number of Urban Areas Wage Index Increasing	221 (53.6%)
Number of Rural Areas Wage Index Increasing	20 (42.6%)
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	123 (29.9 %)
Number of Urban Areas Wage Index Increasing by 5 percent or More	4 (1.0 %)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	12 (25.5%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0 %)
Number of Urban Areas Wage Index Decreasing	189 (45.9 %)
Number of Rural Areas Wage Index Decreasing	20 (42.6 %)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	81 (19.7 %)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	2 (0.5 %)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	8(17 %)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0 %)
Largest Positive Impact for an Urban Area	7.23 %
Largest Positive Impact for a Rural Area	4.25 %
Largest Negative Impact for an Urban Area	5.47 %
Largest Negative Impact for a Rural Area	2.53 %
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	2
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0

These results indicate that a smaller percentage of urban areas (53.6 percent) would benefit from the occupational mix adjustment than would rural areas (57.4 percent).

We also compared the FY 2022 wage data adjusted for occupational mix from the 2019 survey to the FY 2022 wage data adjusted for occupational mix from the 2016 survey. This analysis illustrates the effect on area wage indexes of using the 2019 survey data compared to the 2016 survey data; that is, it shows whether hospitals' wage indexes will increase or decrease under the 2019 survey data as compared to the prior 2016 survey data. Applying the occupational mix adjustment to the wage data, based on the 2019 survey, resulted in the following:

Comparison of the FY 2022 Occupational Mix Adjusted Wage Indexes: 2016 Survey to 2019 Survey	
Number of Urban Areas Wage Index Increasing	198 (48.1%)
Number of Rural Areas Wage Index Increasing	18 (38.3%)
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	109 (26.5 %)
Number of Urban Areas Wage Index Increasing by 5 percent or More	15 (3.6 %)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	10 (21.3%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	3 (6.4 %)
Number of Urban Areas Wage Index Decreasing	214 (51.9 %)
Number of Rural Areas Wage Index Decreasing	29 (61.7 %)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	117 (28.4 %)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	15 (3.6 %)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	19 (40.4 %)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	1 (2.1 %)
Largest Positive Impact for an Urban Area	14.58 %
Largest Positive Impact for a Rural Area	6.1 %
Largest Negative Impact for an Urban Area	10.76 %
Largest Negative Impact for a Rural Area	6.03 %
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	0
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0

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These results indicate that the wage indexes of 52.9 percent of CBSAs overall will decrease due to application of the 2019 occupational mix survey data as compared to the 2016 occupational mix survey data. Further, a larger percentage of urban areas (48.1 percent) will benefit from the use of the 2019 occupational mix survey data as compared to the 2016 occupational mix survey data than will rural areas (38.3 percent).

G. Application of the Rural Floor, Application of the State Frontier Floor, Continuation of the Low Wage Index Hospital Policy, and Budget Neutrality Adjustment

1. Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the rural floor. Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we removed urban to rural reclassifications from the calculation of the rural floor to prevent inappropriate payment increases under the rural floor due to rural reclassifications, such that, beginning in FY 2020, the rural floor is calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103). The rural floor for this FY 2022 proposed rule continues to be calculated without the wage data of hospitals that have reclassified as rural under § 412.103. We did not propose any changes to the rural floor policy for FY 2022. Also, for the purposes of applying the provisions of section 1886(d)(8)(C)(iii) of the Act, effective beginning in FY 2020, we remove the data of hospitals reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. We did not propose any changes to this policy for FY 2022.

Based on the FY 2022 wage index associated with this final rule (which is available via the internet on the CMS website) and based on the calculation of the rural floor without the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 269 hospitals would receive an increase in their FY 2022 wage index due to the application of the rural floor.

Comment: Some commenters expressed their support for the application of the rural floor policy which included support for the continued exclusion of the wage data of hospitals that have reclassified as rural under § 412.103 when calculating the wage index for the rural floor.

Response: We appreciate the commenters' support for the application of the rural floor policy.

Comment: A commenter urged CMS to treat hospitals that classify as rural per the MGCRB, as rural for all instances including the rural floor calculation.

Response: We thank the commenter for their comment about the MGCRB as it relates to the rural floor calculation. According to current policy, hospitals that classify as rural per the MGCRB, may be included in the rural floor calculation.

Comment: Some commenters opposed the continued application of a nationwide rural floor budget neutrality adjustment, noting that the policy does nothing more than benefit a few hospitals and exacerbate a downward spiral of the wage index for low-wage-index hospitals.

Response: We appreciate the commenters' concerns about application of the nationwide rural floor budget neutrality policy. However, as stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56920), for discharges occurring on or after October 1, 2010, for purposes of applying the rural floor, section 3141 of the Affordable Care Act replaced the statewide budget neutrality adjustment policy with the national budget neutrality adjustment policy that was in

place during FY 2008. That is, section 3141 required that budget neutrality for the rural floor be applied ''through a uniform, national adjustment to the area wage index'' instead of within each State beginning in FY 2011 (75 FR 50160). Accordingly, we do not have the authority to calculate rural floor budget neutrality in a State-specific manner.

2. Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the imputed floor policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. We extended the imputed floor policy eight times since its initial implementation, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and expired on September 30, 2018. (We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FYs 2014 through 2019 (78 FR 50589 through 50590, 79 FR 49969 through 49971, 80 FR 49497 through 49498, 81 FR 56921 through 56922, 82 FR 38138 through 38142, and 83 FR 41376 through 41380, respectively) and to the regulations at 42 CFR 412.64(h)(4).) For FYs 2019, 2020, and 2021, hospitals in all-urban states received a wage index that was calculated without applying an imputed floor, and we no longer included the imputed floor as a factor in the national budget neutrality adjustment.

In computing the imputed floor for an all-urban State under the original methodology established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever was higher was multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State.

We adopted a second, alternative methodology beginning in FY 2013 (77 FR 53368 through 53369) to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit another all-urban State, Rhode Island, which had only one CBSA. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then was increased by this factor, the result of which established the State's alternative imputed floor. Under the updated OMB labor market area delineations adopted by CMS beginning in FY 2015, Delaware became an all-urban State, along with New Jersey and Rhode Island, and was subject to an imputed floor as well. In addition, we adopted a policy, as reflected at § 412.64(h)(4)(vi), that, for discharges on or after October 1, 2012, and before October 1, 2018, the minimum wage index value for a State is the higher of the value determined under the original methodology or the value determined under the alternative methodology. The regulations implementing the imputed floor wage index, both the original methodology and the alternative methodology, were set forth at § 412.64(h)(4).

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Thus, effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstates the imputed floor wage index policy for all-urban States, with no expiration date, using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018. As discussed previously, under § 412.64(h)(4)(vi), the minimum wage index value for hospitals in an all-urban State is the higher of the value determined using the original methodology (as set forth at § 412.64(h)(4)(i) through (v)) or the value determined using alternative methodology (as set forth at § 412.64(h)(4)(vi)(A) and (B)) for calculating an imputed floor. Therefore, as provided in § 412.64(h)(vi), we would apply the higher of the value determined under the original or alternative methodology for calculating a minimum wage index, or imputed floor, for all-urban States effective beginning with FY 2022. We note that the rural floor values used in the alternative methodology at § 412.64(h)(4)(vi)(A) and (B) would not include the wage data of hospitals reclassified under § 412.103, because we currently calculate the rural floor without the wage data of such hospitals.

Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In other words, the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act, as amended, must be applied without taking into account the imputed floor adjustment under section 1886(d)(3)(E)(iv) of the Act. When the imputed floor was in effect from FY 2005 through FY 2018, to budget neutralize the increase in payments resulting from application of the imputed floor, we calculated the increase in payments resulting from the imputed floor together with the increase in payments resulting from the rural floor and applied an adjustment to reduce the wage index. By contrast, for FY 2022 and subsequent years, we proposed to apply the imputed floor after the application of the rural floor and to apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor required under section 1886(d)(3)(E)(iv) of the Act.

We note, given the recent enactment of section 9831 of Public Law 117–2 on March 11, 2021, there was not sufficient time available to incorporate the changes required by this statutory provision (which provides for the application of the imputed floor adjustment in a non-budget neutral manner beginning in FY 2022) into the calculation of the provider wage index for the proposed rule. We will include the imputed floor adjustment in the calculation of the provider wage index in the FY 2022 final rule. We note that CMS has posted, concurrent with the issuance of the proposed rule, estimated imputed floor values by state in a separate data file on the FY 2022 IPPS Proposed Rule web page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-*

Payment/AcuteInpatientPPS/index, and an aggregate payment impact for the imputed floor in the Appendix to the proposed rule.

The imputed floor under section 1886(d)(3)(E)(iv) of the Act applies to all-urban States, as defined in new subclause (IV). Section 1886(d)(3)(E)(iv)(IV) provides that, for purposes of the imputed floor wage index under clause (iv), the term all-urban State means a State in which there are no rural areas (as defined in section 1886(d)(2)(D) of the Act) or a State in which there are no hospitals classified as rural under section 1886 of the Act. Under this definition, given that it applies for purposes of the imputed floor wage index, we believe it would be appropriate to consider a hospital to be classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value. Therefore, under the definition at section 1886(d)(3)(E)(iv)(IV) of the Act, ''a State in which there are no hospitals classified as rural under this section'' would include a State that has a rural area but no hospitals that receive the rural area wage index under section 1886(d) of the Act. For purposes of this definition, hospitals redesignated as rural under section 1886(d)(8)(E) of the Act (412.103 rural reclassifications) would be considered classified as rural if they receive the rural wage index; however, hospitals that are deemed urban under section 1886(d)(8)(B) of the Act (in Lugar counties), or are reclassified to an urban area under section 1886(d)(10) of the Act (MGCRB reclassifications) would not be considered classified as rural because they do not receive the rural wage index. In contrast, we note that in the imputed floor policy in effect from FY 2005 through FY 2018, we did not consider a State to qualify for ''all urban status'' if there were one or more hospitals geographically located in the rural area of the State, even if all such hospitals subsequently reclassified to receive an urban area wage index. There is currently one State, Connecticut, that would be eligible for the imputed floor under this aspect of the proposed rule because there are currently no hospitals in Connecticut that are classified as rural under section 1886(d) for purposes of the wage index—in other words, there are no hospitals that receive the rural wage index.

There is currently one rural county in Connecticut. All hospitals in this county are either deemed urban under section 1886(d)(8)(B) of the Act or receive an MGCRB reclassification under section 1886(d)(10) of the Act. While several Connecticut hospitals were approved for rural reclassification under section 1886(d)(8)(E) of the Act, at this point all have received a subsequent urban reclassification under section 1886(d)(10) of the Act.

Additionally, under section 1861(x) of the Act, the term State has the meaning given to it in section 210(h) of the Act. Because section 210(h) of the Act defines the word State to also include the District of Columbia and the Commonwealth of Puerto Rico, Washington, DC and Puerto Rico may also qualify as all-urban States for purposes of the imputed floor if the requirements of section 1886(d)(3)(E)(iv)(IV) of the Act are met. Based on data available for the proposed rule, the following States would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2022: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, DC.

We proposed to revise the regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) to implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021. First, we proposed to make the following revisions to the regulation text to specify that the imputed floor required under section 1886(d)(3)(E)(iv) of the Act would not be applied in a budget neutral manner:

- We proposed to revise the introductory language at § 412.64(e)(4) to state that the budget neutrality adjustment for the imputed floor under paragraph (h)(4) applies only to discharges on or after October 1, 2004 and before October 1, 2018.
- We proposed a conforming revision to § 412.64(e)(1)(ii) to refer to § 412.64(h)(4)(vii) (proposed in the proposed rule) in the introductory phrase that excepts certain provisions from the budget neutrality requirement specified in paragraph (e)(1)(ii).
- We proposed to revise § 412.64(h)(4) to add a new clause (vii) stating that, for discharges on or after October 1, 2021, the minimum wage index computed under this paragraph may not be applied in a budget neutral manner.

In addition, we proposed to revise the introductory language at § 412.64(h)(4) to specify that the minimum wage index and methodology described in that paragraph also apply for discharges on or after October 1, 2021. Further, we proposed to revise § 412.64(h)(4)(vi) to specify that this clause also applies to discharges on or after October 1, 2021.

Finally, we proposed to make the following revisions to § 412.64(h)(5). First, we proposed to redesignate the current language at § 412.64(h)(5) as § 412.64(h)(5)(i) and to revise this language to reflect that it applies for purposes of applying the imputed floor for discharges on or after October 1, 2004 and before October 1, 2018. Second, we proposed to add a new clause (ii) to § 412.64(h)(5) to reflect the proposed definition of all-urban State for purposes of applying the imputed floor for discharges on or after October 1, 2021, as previously discussed. Specifically, we proposed at § 412.64(h)(5)(ii) that, for purposes of applying the imputed floor for discharges on or after October 1, 2021, an all-urban State is a State with no rural areas, as defined in § 412.64, or a State in which there are no hospitals classified as rural under section 1886 of the Act. We are further proposing at § 412.64(h)(5)(ii) that a hospital would be considered classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

Comment: Several commenters supported the proposed implementation of the imputed floor wage index policy to benefit all-urban states. A commenter opposed the reinstatement of the imputed floor, stating that it exacerbates wage index disparities, but acknowledged that CMS followed legislation enacted by Congress. This commenter requested CMS include details by state of the effects of the imputed rural floor. Commenters both in support and in opposition of the imputed floor policy applauded its implementation without the application of budget neutrality, per section 9831 of the American Rescue Plan Act of 2021. A commenter specifically concurred with CMS' interpretation that the definition of an all-urban state according to section 9831 of the American Rescue Plan Act of 2021 is one in which no hospital receives the rural area wage index.

Response: We appreciate the commenters' support of our proposed implementation of the imputed floor. Responding to the commenter opposed to this policy, we underscore that, as the commenter itself pointed out, the imputed floor has been enacted into law via section 9831 of the American Rescue Plan Act of 2021. Accordingly, CMS does not have discretion to not adopt this policy. In response this commenter's request for details by state of the effects of the imputed rural floor, we direct the commenter to the data file that CMS posted concurrent with the proposed rule with estimated imputed floor value by state at *https://*

www.cms.gov/files/zip/fy2022-ipps-nprm-imputed-state-floors.zip. Finally, we agree with the commenter that CMS' implementation of the imputed floor is consistent with the exemption from budget neutrality and the definition of an all-urban state according to section 9831 of the American Rescue Plan Act of 2021.

Comment: A commenter requested that CMS clarify whether a hospital that is assigned the imputed floor wage index value would be treated as if the hospital is physically located in a geographically rural area. The commenter requested that CMS confirm that receipt of the imputed floor wage index would confer rural status for provisions such as RRC qualification, GME, DSH, and MGCRB reclassification.

Response: A hospital that receives the imputed floor wage index is not considered rural. In fact, the imputed floor policy by definition applies only to all-urban states. The commenter might be referring to § 412.103 urban to rural reclassifications, which does confer rural status for certain purposes; the imputed floor simply sets a minimum wage index in an all-urban state, but does not change the status of the hospital. Accordingly, the imputed floor wage index would not confer rural status for the aforementioned provisions.

After consideration of the public comments, we are finalizing without modification our proposed revisions to the regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) to implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021.

3. State Frontier Floor for FY 2022

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25407), we did not propose any changes to the frontier floor policy for FY 2022. In the proposed rule, we stated that 44 hospitals would receive the frontier floor value of 1.0000 for their FY 2022 proposed wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming.

We did not receive any public comments on the application of the State frontier floor for FY 2022. In this final rule, 44 hospitals will receive the frontier floor value of 1.0000 for their FY 2022 wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.0000.

The areas affected by the rural and frontier floor policies for the final FY 2022 wage index are identified in Table 2 associated with this final rule, which is available via the internet on the CMS website.

4. Continuation of the Low Wage Index Hospital Policy; Budget Neutrality Adjustment

To help mitigate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications under 42 CFR 412.103 in the rural floor, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized policies to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor. We also provided for a transition in FY 2020 for hospitals experiencing significant decreases in their wage index values as compared to their final FY 2019 wage index, and made these changes in a budget neutral manner.

We increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals (the low wage index hospital policy). We stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) that this policy will be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Therefore, the policy will continue in FY 2022. In order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, for FY 2022 and for subsequent fiscal years during which the low wage index hospital policy is in effect, we proposed to apply a budget neutrality adjustment in the same manner as we applied it in FY 2021, as a uniform budget neutrality factor applied to the standardized amount. We refer readers to section II.A.4.b. of the addendum to this final rule for further discussion of the budget neutrality adjustment for FY 2022. For purposes of the low wage index hospital policy, based on the data for the final rule, the table displays the 25th percentile wage index value across all hospitals for FY 2022.

FY 2022 25th Percentile Wage Index Value	0.8437

Comment: Many commenters thanked CMS for continuing the low wage index policy to significantly help struggling low-wage hospitals and promote equity among providers. These commenters specifically applauded CMS increasing the wage index values of low-wage hospitals. Several commenters requested that CMS extend the policy beyond four years as originally stated in the FY 2020 IPPS final rule when the policy was finalized, with a commenter specifically requesting the policy be finalized for a ten-year period. Other commenters similarly supported the policy but maintained that CMS needs to do more to address wage index disparities facing rural and low-wage providers, particularly considering the devastating effects of the COVID–19 pandemic on hospitals. Alternative solutions suggested by the commenters included a national rural wage index; an urban wage index floor of 1.0000; and wage data audits to verify local labor prices.

Response: We appreciate the many comments received in support of our policy to provide an increase in the wage index for hospitals with wage index values below the 25th percentile wage index value for a year (referred to as the low wage index hospital policy). We note that we did not propose any changes to this policy in the FY 2022 IPPS/LTCH PPS proposed rule. We appreciate the commenters' requests to extend this policy beyond four years as well as other suggested alternatives. Because we consider these comments to be outside the scope of the FY 2022 IPPS/LTCH PPS proposed rule, we are not addressing them in this final rule but may consider them in future rulemaking.

Comment: We also received many comments opposing the continuation of the low wage index hospital policy. The commenters expressed that the policy fails to recognize legitimate differences in geographic labor markets. A commenter questioned CMS' statutory authority to promulgate this policy under 42 U.S.C. 1395ww(d)(3)(E) because inflating the wage index for the lowest quartile creates a wage index system not based on actual wages paid

by these hospitals. A few commenters maintained that the low wage policy is not well targeted and is ineffective. A commenter pointed to a recent OIG report that suggests a complicated set of issues in local labor markets determines hospital wages in addition to Medicare payment rates. The commenter requested that CMS repeal the low wage index policy for FY 2022 while it pursues the OIG's recommendation for CMS to study the reasons some hospitals in a particular area were able to pay higher wages than others in the same area prior to the implementation of the low wage index hospital policy.

Response: We believe we addressed the commenters' concerns in our response to comments when we first promulgated the policy, and we refer readers to that discussion (84 FR 42325 through 42328). Specifically, in response to the commenters opposing our policy because they assert the policy fails to recognize differences in geographic labor markets, we continue to believe, for the reasons stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42327–42328), that by preserving the rank order in wage index values, our policy continues to reflect meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas. Furthermore, as stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42327 through 42328), we believe that the low wage index hospital policy increases the accuracy of the wage index as a relative measure of wages across different geographic regions because it allows low wage index hospitals to increase their employee compensation in ways that we would expect if there were no lag in reflecting compensation adjustments in the wage index. Thus, under the low wage index hospital policy, we believe the wage index for low wage index hospitals appropriately reflects the relative hospital wage level in those areas compared to the national average hospital wage level. As explained in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331), because the low wage index hospital policy results in a wage index that is based on the actual wage data we collect from hospitals, it falls within the scope of the authority in section 1886(d)(3)(E) of the Act, which requires that the wage index be constructed ''on the basis of'' that data.

Relying in part on an OIG report about the policy, some commenters stated that our policy is mis-targeted and ineffective. We believe, however, that the numerous comments received in support of this policy indicate that many low wage hospitals are indeed helped by this policy. More importantly, refining our criteria to target a subset of low-wage hospitals as the commenter suggests, such as low-wage hospitals that are rural or that have negative profit margins, would not maintain the rank order in wage index values. As we stated earlier, we believe that maintaining the rank order of wage index values is important to reflect meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas. Even several commenters that disagreed with our policy stressed the need for the wage index to be an accurate measure of the *relative* level of wages in different areas. A highly targeted approach that selected individual hospitals for relief would not maintain the rank order of wage index values and thus would be inconsistent with the construction of a relative measure of area wage levels. While it might be possible to refine our criteria for a more targeted approach, we believe it is reasonable to conclude that our current policy will have the intended effect of providing the opportunity for low wage hospitals to increase compensation. As we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42327), the future wage data from those hospitals will help us assess our reasonable expectation that hospitals will increase their employee compensation as a result of wage index increases under this policy. Once the increased employee compensation is reflected in the wage data, there may be no need for the continuation of the policy, given that we would expect the resulting increases in the wage index to continue after the temporary policy is discontinued.

Commenters that referenced the OIG report pointed out that the report indicates that Medicare payment is only one factor contributing to hospitals' low wages. While we recognize that Medicare payment is not the only factor driving hospital wages, Medicare payment is a contributing factor to hospital wage levels that is within the purview of CMS, unlike factors such as local housing markets. Therefore, we continue to believe it is appropriate to keep this policy in place while we evaluate its effectiveness. As we stated earlier in response to this comment, while the OIG report indicates that there may be ways to refine our policy, it does not show that our current policy approach is unreasonable or suggest the policy goal we are hoping to achieve is unworthy. Nor does the OIG report suggest we lack authority to pursue that goal. At most the OIG report suggests there might be alternative approaches to the problem. Therefore, we disagree with the commenter's suggestion that we repeal the low wage index hospital policy currently in place to study the OIG's recommendations. Due to the four year data lag until a hospital's wages are reflected in the wage index, we believe that keeping the policy in place for the full four year period that was finalized in the FY 2020 IPPS/LTCH PPS final rule will enable us to evaluate whether the policy achieved its intended effects. Prematurely pausing this policy, as the commenter suggests, could hamper the potential effectiveness of this policy in providing low wage hospitals an opportunity to increase compensation, which may in turn raise their wage index.

In response to the comment suggesting that CMS study the reasons hospitals are able to pay higher wages, we note that CMS has extensively studied wage disparities and contributing factors to low wage indexes in the past. In the FY 2019 IPPS LTCH/PPS proposed rule (83 FR 20372), CMS issued a request for information engaging multiple stakeholders on wage index disparities. As summarized in the FY 2020 IPPS/LTCH PPS proposed and final rules (84 FR 19394 and 84 FR 42326–42332, respectively) many stakeholders expressed that circularity, where low wage hospitals remain locked in a downward spiral due to low wage indexes that prevent them from raising their wages, was the most important wage index issue facing the system and it needed to be addressed quickly. The low wage index hospital policy was developed as a result of extensive analysis and engagement with multiple stakeholders. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326–42332) for further discussion of the low wage index hospital policy and our responses to similar comments.

Therefore, while the OIG report suggests that we do further study before implementing any policy regarding low wage hospitals, we note that we had already promulgated the policy by the time of the OIG report, and that we have been studying this issue for several years. We believe there was more than a sufficient basis on which to conclude that it was appropriate to take immediate action in the form of the policy we finalized and to continue to assess the results of that policy and to otherwise continue to analyze the issue. Doing further study might have resulted in a policy some might have preferred being implemented sometime in the future, but we concluded that the problem needed addressing now. Again, we believe the many comments we

received in favor of the policy support this judgment. We agree with the OIG that the issue deserves more study, and we will continue to engage in that, but we believe the best course was to implement our policy now while we engage in that study.

Comment: Many commenters supported increasing the wage index values of low-wage hospitals, but urged CMS to do so in a non-budget-neutral manner. Commenters asserted that this redistribution forces high-wage, mostly urban hospitals to bear the cost of supporting lower-wage hospitals. Commenters who opposed the low wage index hospital policy also disagreed with the budget neutrality adjustment, stating that the budget neutrality adjustment penalizes many hospitals, including rural hospitals. Some commenters stated that 42 U.S.C. 1395ww(d)(5)(I) does not authorize budget neutrality adjustments to the national standardized amount, except for transfer cases. Other commenters requested that CMS ensure that the budget neutrality adjustment factor not apply to hospitals falling below the 25th percentile or revert to its FY 2020 proposal to decrease the wage index for hospitals with values above the 75th percentile. A few commenters stated that the wage index increase for hospitals between the 22nd and the 25th percentile is negated by the reduction to the standardized rate.

Response: We disagree with the commenters that the low wage index hospital policy should be implemented in a non-budget neutral manner. As we stated in response to similar comments in the FY 2020 IPPS/LTCH PPS final rule, (84 FR 42331 and 42332), under section 1886(d)(3)(E) of the Act, the wage index adjustment is required to be implemented in a budget neutral manner. However, even if the wage index were not required to be budget neutral under section 1886(d)(3)(E) of the Act, we would consider it inappropriate to use the wage index to increase or decrease overall IPPS spending. As we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331), the wage index is not a policy tool but rather a technical adjustment designed to be a relative measure of the wages and wage-related costs of subsection (d) hospitals. As a result, as we explained in the FY 2020 IPPS/LTCH PPS final rule, if it were determined that section 1886(d)(3)(E) of the Act does not require the wage index to be budget neutral, we invoke our authority at section 1886(d)(5)(I) of the Act in support of such a budget neutrality adjustment. We have considered the commenters' suggestion that we do not have authority under section 1886(d)(5)(I) of the Act to implement a budget neutrality adjustment to the national standardized amount, including the argument that such authority exists only with respect to transfer cases. Contrary to the commenters' suggestion, and consistent with our response to a similar comment in the FY 2020 and FY 2021 IPPS/LTCH PPS final rules, we believe that we have broad authority under section 1886(d)(5)(I) of the Act to promulgate a budget neutrality adjustment to the national standardized amount and that this authority is not limited to transfer cases. We refer readers to the full discussion of budget neutrality for the low wage index hospital policy in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42328–42332).

With regard to the commenter's assertion about a possible reduction to overall payment if the amount of benefit received from the wage index boost is less than the reduction to the standardized rate, we believe we have applied both the quartile policy and the budget neutrality policy appropriately. The quartile adjustment is applied to the wage index, which resulted in an increase to the wage index for hospitals below the 25th percentile. The budget neutrality adjustment is applied to the standardized amount in order to ensure that the low wage index hospital policy is implemented in a budget neutral manner. Thus, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act and with how we implemented budget neutrality for the low wage index hospital policy in FY 2020, we believe it is appropriate to continue to apply a budget neutrality adjustment to the national standardized amount for all hospitals so that the low wage index hospital policy is implemented in a budget neutral manner for FY 2022.

After consideration of the public comments we received, for the reasons discussed in this final rule and in the FY 2022 IPPS/LTCH PPS proposed rule, we are finalizing our proposal, without modification, to apply a budget neutrality adjustment for our low wage index hospital policy in the same manner as we applied it in FY 2020 and FY 2021, as a uniform budget neutrality factor applied to the standardized amount.

As we stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25407 through 25409), we will continue to apply the policies we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 32715) to address wage index disparities—that is, the low wage index hospital policy, and the exclusion of the wage data of hospitals reclassified under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) from the rural floor and from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. For purposes of the low wage index hospital policy, based on the data for this final rule, for FY 2022, the 25th percentile wage index value across all hospitals is 0.8437.

H. FY 2022 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). In this FY 2022 IPPS/LTCH PPS final rule, as provided beginning with the FY 2021 IPPS/LTCH PPS final rule, we have included Table 4A which is titled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' and Table 4B titled ''Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties).'' We refer readers to section VI. of the Addendum to this final rule for a discussion of the wage index tables for FY 2022.

I. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). We note that this deadline was extended for applications for FY 2022 reclassifications to 15 days after the public display date of the FY 2021 IPPS/LTCH final rule at the Office of the Federal Register, using our authority under section 1135(b)(5) the Act due to the COVID–19 Public Health Emergency. Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics

similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). We note that rural hospitals reclassifying under the MGCRB to another State's rural area are not eligible for the rural floor, because the rural floor may apply only to urban, not rural, hospitals.

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103 from the calculation of the rural floor. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. We exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930) for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For a discussion on the effects of reclassifications under § 412.103 on the rural area wage index and the calculation of the rural floor, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336).

We refer readers to the interim final rule with comment period (IFC) (CMS–1762–IFC) simultaneously submitted for public inspection with the proposed rule implementing the court's decision in *Bates County Memorial Hospital* v. *Azar,* 464 F. Supp. 3d 43 (D.D.C. 2020) (''*Bates*'') for further changes to the treatment of § 412.103 hospitals reclassifying under the MGCRB.

Comment: A commenter disagreed with CMS' treatment of hospitals with dual § 412.103 and MGCRB reclassifications. The commenter stated that CMS' policy of considering the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation violates the statutory requirement to treat § 412.103 hospitals as located in the rural area of the state. The commenter specifically requested that CMS include the wages of § 412.103 hospitals that also have an active MGCRB reclassification in calculating the rural wage of the state if not doing so would reduce the wage index for that area, in the same manner that geographically rural hospitals with a MGCRB reclassification are treated according to § 1886(d)(8)(C)(ii).

Response: We appreciate the commenter's input. We note that CMS includes the wage data of § 412.103 hospitals that do not have an MGCRB reclassification in the rural area wage index, consistent with the statutory requirement to treat § 412.103 hospitals as rural. CMS continues to treats § 412.103 hospitals as rural even if such hospitals have an additional MGCRB reclassification by according the hospital the benefits of rural status, such as 340B program and RRC eligibility. However, in developing our policies for how hospitals with dual reclassifications would be treated in wage index calculations following our April 21, 2016 IFC (81 FR 23428 through 23438), CMS discussed the effect of simultaneous § 412.103 and MGCRB reclassifications. We stated that when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification would control for wage index calculation and payment purposes. We explained that ''In these circumstances, we believe it is appropriate to rely on the urban MGCRB reclassification to include the hospital's wage data in the calculation of the urban CBSA wage index. Further, we believe it is appropriate to rely on the urban MGCRB reclassification to ensure that the hospital be paid based on its urban MGCRB wage index. While rural reclassification confers other rural benefits besides the wage index under section 1886(d) of the Act, a hospital that chooses to pursue reclassification under the MGCRB (while also maintaining a rural reclassification under § 412.103) would do so solely for wage index payment purposes.'' (81 FR 23434). We continue to believe that that policy, developed through rulemaking, is appropriate. Since we did not propose to change our current policy in the FY 2022 IPPS/LTCH PPS proposed rule, we are not making any changes to this policy in this final rule.

With regard to the application of the hold harmless policy that the commenter referenced at § 1886(d)(8)(C)(ii), the statute requires that a rural area be held harmless from the effects of hospitals reclassifying under Lugar or the MGCRB. Specifically, § 1886(d)(8)(C)(ii) states: ''If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as not being located in the rural area in a State, reduces the wage index for that rural area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection as if the hospitals so treated had not been excluded from calculation of the wage index for that rural area.''

The commenter suggests CMS include the wage data of hospitals with § 412.103 reclassifications in the rural area of the State referenced in

§ 1886(d)(8)(C)(ii). The rural area wage index, which according to the commenter should include § 412.103 hospitals, would be compared to a wage index with the effect of MGCRB reclassifications and Lugar hospital statuses applied, in order to possibly hold the rural area harmless from the effect of MGCRB reclassifications and Lugar hospital statuses. There would be numerous downstream effects of such a policy across IPPS ratesetting that might harm hospitals, contrary to the commenter's intent. For example, using the data associated with this final rule, some states would experience a decline of up to 4.8 percent in their rural wage index if we were to treat hospitals with dual § 412.103 and MGCRB reclassifications no differently than geographically rural hospitals with MGCRB reclassifications, as the commenter suggests. In another example, such a policy would potentially create barriers to MGCRB reclassification for rural and § 412.103 hospitals. If CMS were to treat § 412.103 hospitals in the manner the commenter requests by considering such hospitals' data in the rural area prior to reclassification, then § 412.103 hospitals would have the state's rural area listed as their geographic CBSA in the Three Year Average Hourly Wage (AHW) File used for MGCRB reclassification. As commenters expressed in comments responding to our May 10, 2021 interim final rule with comment period (CMS–1762–IFC) and summarized in section III.K.3. of the preamble of this final rule, assigning the rural CBSA as the geographic CBSA for § 412.103 hospitals in the Three Year AHW File would potentially hamper geographically rural and § 412.103 hospitals' ability to reclassify. Many geographically rural and § 412.103 hospitals would no longer be able to satisfy the wage comparison criteria at § 412.230(d)(1)(iii)(C) (requiring a hospital's average hourly wage to be at least 106 percent of the average hourly wage of all other hospitals in the area in which the hospital is located) if the wages of high-wage § 412.103 hospitals are included in the area in which the hospital is located prior to reclassification. Notably, commenters unanimously requested CMS require § 412.103 hospitals to compare their AHW to the AHW of only hospitals actually located in the rural area, exclusive of hospitals with § 412.103 rural redesignations, for simplicity because hospitals may obtain a § 412.103 reclassification at any time and would change the rural area's AHW and because including § 412.103 reclassifications will change the rural areas AHW.

We did not propose the policy the commenter suggests, and it would constitute a significant change with numerous effects on the IPPS wage index, as enumerated above. We do not think it would be appropriate to adopt such a policy without describing it in a proposed rule and obtaining public comments from all relevant stakeholders. Therefore, in this final rule we are not adopting the policy the commenter suggested, but will consider further addressing the issue in future rulemaking.

2. MGCRB Reclassification and Redesignation Issues for FY 2022

a. FY 2022 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. At the time this final rule was constructed, the MGCRB had completed its review of FY 2022 reclassification requests. Based on such reviews, there are 406 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2022. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2022, hospitals reclassified beginning in FY 2020 or FY 2021 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 243 hospitals approved for wage index reclassifications in FY 2020 that will continue for FY 2022, and 291 hospitals approved for wage index reclassifications in FY 2021 that will continue for FY 2022. Of all the hospitals approved for reclassification for FY 2020, FY 2021, and FY 2022, based upon the review at the time of the proposed rule, 940 hospitals are in a MGCRB reclassification status for FY 2022 (with 140 of these hospitals reclassified back to their geographic location).

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

Finally, we note that in the FY 2021 IPPS/LTCH final rule (85 FR 58771—58778), CMS finalized an assignment policy for hospitals reclassified to CBSAs from which one or more counties moved to a new or different urban CBSA under the revised OMB delineations based on OMB Bulletin 18–04. We provided a table in that rule (85 FR 58777 and 58778) which described the assigned CBSA for all the MGCRB cases subject to this policy. For such reclassifications that continue to be active or are reinstated for FY 2022 (and FY 2023, if applicable), the CBSAs assigned in the FY 2021 IPPS/LTCH final rule continue to be in effect.

b. Revisions to the Regulations at § 412.278 for Administrator's Review

The regulation at § 412.278(b) addresses the procedure for a hospital's request for the Administrator's review of an MGCRB decision. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58788), we eliminated the prohibition on submitting a request by facsimile or other electronic means so that hospitals may also submit requests for Administrator review of MGCRB decisions electronically. In addition, we updated the regulation at § 412.278(b)(1) to require the hospital to submit an electronic copy of its request for review to CMS' Hospital and Ambulatory Policy Group. We specified that copies to CMS' Hospital and Ambulatory Policy Group should be submitted via email to wage *index@cms.hhs.gov*. In the proposed rule, we proposed to further revise the regulation at § 412.278(b)(1) to specify that the hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor, in the manner directed by the

Office of the Attorney Advisor. We believe that this additional language would provide clarity and specificity by addressing any changes to the future technology platform for submission of the hospital's request for Administrator review. Hospitals will continue to be notified of the procedure for requesting Administrator review in the decision letters issued by the MGCRB.

The regulation at § 412.278(f)(2) addresses the timing for the Administrator's decision. Specifically, the Administrator issues a decision in writing to the party with a copy to CMS not later than 90 calendar days following the receipt of the party's request for review (§ 412.278(f)(2)(i)), or not later than 105 calendar days following issuance of the MGCRB decision in the case of review at the discretion of the Administrator (§ 412.278(f)(2)(ii)). While the regulation at § 412.278(f)(2)(i) allows the Administrator to toll the 90-day timeframe for good cause, the regulation at § 412.278(f)(2)(ii) does not expressly provide for tolling the 105 day timeframe in the case of review at the discretion of the Administrator. We believe the policy regarding tolling should be the same regardless of whether the Administrator exercises review at the request of the hospital or at her discretion. Therefore, we proposed to also provide for tolling of the 105-day timeframe at § 412.278(f)(2)(ii). Specifically, we proposed to revise § 412.278(f)(2)(ii) to state that the Administrator issues a decision in writing to the party with a copy to CMS not later than 105 days following issuance of the MGCRB decision in the case of review at the discretion of the Administrator, except the Administrator may, at his or her discretion, for good cause shown, toll such 105 days. We received no comments on this proposal and therefore are finalizing the proposed revisions to §§ 412.278(b)(1) and 412.278(f)(2)(ii) without modification.

3. Redesignations Under Section 1886(d)(8)(B) of the Act (Lugar Status Determinations)

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in that rule, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov*. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov*. To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an out-migration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the outmigration adjustment would be denied, and the hospital would be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values would be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it would be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act.

J. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new outmigration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation

of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in prior IPPS/LTCH PPS final rules, most recently in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58787), we have applied the same policies, procedures, and computations since FY 2012. We proposed to use them again for FY 2022, as we believe they continue to be appropriate for FY 2022. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2022, the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate. For FY 2022, we did not propose any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).)

Comment: A teaching hospital located in a rural area explained that itis disadvantaged by the current wage index policy because other hospitals in its state are able to benefit from higher wage areas due to the out-migration adjustment, which the commenter stated is currently unavailable to it. According to the commenter, despite being ineligible for an out-migration adjustment, it continues to complete for labor with hospitals located in urban areas. As such, the commenter would like CMS to consider the impact that the current wage index policies has on it and other teaching hospitals like it that are located in rural areas, are ineligible for the out-migration adjustment and serve a sparsely populated patient service area but compete for labor with an urban area with a high concentration of similar institutions.

Response: We appreciate the commenter's concerns. Wage index policy, specifically the out-migration adjustment based on commuting patterns of hospital employees, is applied according to the statute described at section 1886(d)(13) of the Act. As described earlier in this section, the out-migration adjustment is based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate.

For the reasons set forth in this final rule and in the FY 2022 IPPS/LTCH PPS proposed rule, for FY 2022, we are finalizing our proposal, without modification, to continue using the same policies, procedures, and computations that were used for the FY 2012 out-migration adjustment and that were applicable for FYs 2016 through 2021.

Table 2 associated with this final rule (which is available via the internet on the CMS website) includes the proposed out-migration adjustments for the FY 2022 wage index. In addition, Table 4A associated with this final rule, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' (also available via the internet on the CMS website) consists of the following: A list of counties that are eligible for the out-migration adjustment for FY 2022 identified by FIPS county code, the final FY 2022 out-migration adjustment, and the number of years the adjustment will be in effect.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act Implemented at 42 CFR 412.103

1. Application for Rural Status and Lock-in Date

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336) for a discussion on our current policy to calculate the rural floor without the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103.

Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) that we believed there should be a definitive timeframe within which a hospital must apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year's wage data used for setting payment rates. Therefore, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931 through 56932), we revised § 412.103(b) by adding paragraph (6) to add a lock-in date by which a hospital's application for rural status must be filed in order to be treated as rural in the wage index and budget neutrality calculations for payment rates for the next Federal fiscal year. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41384 through 41386), we changed the lock-in date to provide for additional time in the ratesetting process and to match the lock-in date with another existing deadline, the usual public comment deadline for the IPPS proposed rule. We revised § 412.103(b)(6) to specify that, in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2) and (4), and (h) for payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103 no later than 60 days after the public display date at the Office of the Federal Register of the IPPS proposed rule for the next Federal fiscal year.

The lock-in date does not affect the timing of payment changes occurring at the hospital-specific level as a result of reclassification from urban to rural under § 412.103. As we discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41385 through 41386), this lock-in date also does not change the current regulation that allows hospitals that qualify under § 412.103(a) to request, at any time during a cost reporting period, to reclassify from urban to rural. A hospital's rural status and claims payment reflecting its rural status continue to be effective on the filing date of its reclassification application, which is the date the CMS Regional Office receives the application, in accordance with § 412.103(d). The

hospital's IPPS claims will be paid reflecting its rural status beginning on the filing date (the effective date) of the reclassification, regardless of when the hospital applies.

2. Changes to Cancellation Requirements at § 412.103(g)

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42322), we noted that if an application is approved by the CMS Regional Office after our ratesetting lock-in date, the final rule rural wage index value would most likely not include the data for this hospital in the ratesetting calculation. Therefore, we noted that this may incentivize relatively low wage index hospitals to time their applications to avoid reducing the State's rural wage index. These hospitals could then conceivably cancel their rural reclassifications (effective for next FY), and then reapply again after the 'lock-in date.' We stated in the FY 2020 IPPS/LTCH PPS final rule that we planned to monitor this situation over the course of FY 2020, and determine if it is necessary to take action to prevent this type of gaming in future rulemaking.

We stated in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58788) that hospitals in certain states were indeed timing their rural reclassifications and applications to exploit the rural reclassification process in order to obtain higher wage index values. For example, for FY 2020, at least twenty-one hospitals in one State obtained § 412.103 rural reclassifications after the FY 2020 lock-in date, effectively receiving their State's rural wage index without having their wage data included, which would have lowered their State's rural wage index. These hospitals then requested to cancel their § 412.103 rural reclassifications effective for FY 2021, in accordance with § 412.103(g)(3). Similarly, five hospitals in another State, hospitals with wage data that would have lowered their State's FY 2021 rural wage index, requested to cancel their § 412.103 rural reclassifications for FY 2021, so that the rural wage index would be set using the data of one geographically rural hospital and two hospitals reclassified under § 412.103 that withdrew their MGCRB reclassifications for FY 2021. All five of these hospitals that withdrew their rural reclassification effective October 1, 2021 have since reapplied and been approved for rural reclassification. At least a dozen additional hospitals in this State were also approved for rural reclassification during FY 2021. By timing their applications to be approved after the lock-in date, these hospitals are receiving a higher rural wage index without having their own data included in the rural wage index calculation. We believe this practice of applying for and canceling rural reclassification to manipulate a State's rural wage index is detrimental to the stability and the accuracy of the Medicare wage index system.

In the FY 2008 IPPS/LTCH final rule (72 FR 47371 through 47373), CMS addressed an issue of hospitals applying for rural reclassification and then requesting cancelation soon after approval. Certain hospitals were using rural reclassifications to obtain RRC status, then canceling their rural reclassification so they could obtain an MGCRB reclassification, and using their prior RRC status in order to benefit from favorable MGCRB reclassification rules. To address this, CMS finalized a policy that required such hospitals to maintain rural status for one full cost reporting year before their rural reclassification could be canceled (cancellation was not effective until the hospital had been paid as rural for at least one 12-month cost-reporting period, and not until the beginning of the FY following the request for cancellation and the 12-month cost reporting period (§ 412.103(g)(2)(ii)). As discussed in the FY 2008 IPPS/LTCH proposed rule (72 FR 24812), we stated that we believed this policy was reasonable, given that acquired rural status for IPPS hospitals should be a considered decision for hospitals that truly wish to be considered as rural, and not purely as a mechanism for reclassifying. In the April 21, 2016 interim final rule with comment period (81 FR 23428 through 23438)), CMS implemented provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. In the FY 2020 IPPS/LTCH final rule (42320 through 42321), CMS removed the requirement that RRCs must be paid as rural for one cost reporting year before canceling rural reclassification, as there no longer was an incentive to obtain and then cancel rural reclassification status to obtain an MGCRB reclassification. However, given our observations over the past two fiscal years of a new form of wage index gaming, as described in the previous paragraph, we believe it is necessary and appropriate to adopt a similar measure to prevent rural reclassifications from being used purely as a mechanism for statewide wage index manipulation.

Specifically, we proposed that requests to cancel rural reclassifications must be submitted to the CMS Regional Office not earlier than one calendar year after the reclassification effective date. For example, a hospital that was approved to receive a rural reclassification effective October 1, 2021 would not be eligible to request cancellation until October 1, 2022. We also proposed an additional modification to the effective date of these cancellation requests. Currently, all rural reclassification cancellation requests must be submitted not less than 120 days before the end of a fiscal year (that is, assuming the fiscal year ends on September 30th, no cancellation requests may be submitted after June 2nd and before October 1st). This timeframe typically aligns closely with the rural reclassification lock-in date under § 412.103(b)(6) (the hospital's rural reclassification application must be approved by the CMS Regional Office no later than 60 days after the public display date of the IPPS/LTCH PPS proposed rule at the Office of the Federal Register in order for a hospital to be treated as rural in the wage index and budget neutrality calculations for the next Federal fiscal year). The lock-in date and the 120 day cancellation deadline provide timeframes within which a hospital must be approved for rural reclassification (to have its rural status included in the wage index and budget neutrality calculations for the next fiscal year) or request cancellation of rural status, respectively, and also give CMS adequate time to incorporate these changes in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2) and (4), and (h) for payment rates for the next Federal fiscal year. Rural reclassifications are effective as of the date the application is received (§ 412.103(b)(5), (d)), and CMS Regional Offices are required to render a determination within 60 days of receipt of the application (§ 412.103(c)). We believe that even with the proposed one-year minimum reclassification period before cancellation can be requested, there still would be a possibility that hospitals could time their applications around the lock-in date and 120 day deadline to continue to manipulate the State's rural wage index calculation. For example, assuming the lock-in date for a given year was May 30th (that is, the date by which the Regional Office must approve the application in order for the rural reclassification to be included in the wage index and budget neutrality calculations for the upcoming fiscal year), a hospital may choose to apply for rural reclassification on May 25th, virtually assuring that it could not be approved in time to be considered for wage index development purposes for the upcoming fiscal year. Assuming our

one-year minimum reclassification period proposal is finalized, the hospital could request cancellation on May 25th the following year. Since that date would be prior to 120 day cancellation deadline, a hospital could once again cancel its rural reclassification, then reapply for rural reclassification status, and once again receive the rural wage index for the upcoming fiscal year while excluding its own wage data from the calculation. To address this rural wage index manipulation, we proposed to eliminate the current rule at § 412.103(g)(3) (that cancellation must be requested 120 days prior to the end of the fiscal year and is effective beginning with the next fiscal year) and replace it with a policy that ensures that a hospital approved for rural reclassification (and that does not receive an additional reclassification) would have its data included in the calculation of the rural wage index for at least one Federal fiscal year before the rural reclassification status could be canceled. Specifically, we proposed to make cancellation requests effective for the Federal fiscal year that begins in the calendar year after the calendar year in which the cancellation request is submitted. For example, we proposed that a cancellation request submitted on December 31, 2021 would be effective October 1, 2022. But a cancellation request submitted one day later on January 1, 2022 would not become effective until October 1, 2023.

Specifically, we proposed to add 412.103(g)(4) to state that for all written requests submitted by hospitals on or after October, 1, 2021 to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 1 calendar year after the effective date of the rural reclassification. The hospital's cancellation of its rural reclassification would be effective beginning the Federal fiscal year that begins in the calendar year following the calendar year in which the cancellation request is submitted. We proposed to make conforming revisions to § 412.103(g)(3) to reflect that the rule in § 412.103(g)(3) applies to requests for cancellation of rural reclassification submitted on or after October 1, 2019 and before October 1, 2021.

We considered an alternative policy to increase the current 120 day cancellation deadline to a sufficient number of days to ensure that hospitals could not time applications and cancellations to straddle the lock-in date. Given the floating nature of the lock-in date due to the publication of the proposed rule varying year to year, it is difficult to determine how long that period would need to be in order to ensure our policy goals of preventing rural wage index manipulation are met. We acknowledge that our proposals would increase the amount of time a hospital must retain rural reclassification before it could cancel that status. However, we do not believe these proposed changes would have an undue impact on hospitals. In the FY 2021 final rule, 81 percent of hospitals with rural reclassifications were assigned a wage index based on an MGCRB or ''Lugar'' reclassification, and would not receive a wage index based on their rural reclassification.[758] Another 11 percent received a rural wage index value that was greater than or equal to their geographically urban area. Since these hospitals are typically benefiting by maintaining rural reclassification status, we do not believe they would be negatively affected by our proposals. More than half of the remaining 9 percent of hospitals with rural reclassifications do so to maintain MDH or SCH status. These special statuses convey additional financial benefits to hospitals and are not typically or routinely canceled by hospitals. We note that in the FY 2008 IPPS/LTCH final rule (72 FR 47372), we addressed a comment that expressed concern that the proposed requirement that a hospital must maintain rural status for at least a full 12 months could adversely affect hospitals with SCH status since the payment rate as a rural SCH may be only slightly higher than the urban Federal rate. Since the form of wage index manipulation addressed by the proposed policy in FY 2008 specifically involved hospitals acquiring rural status to become RRCs, CMS opted to limit the policy finalized in FY 2008 to RRCs only. By contrast, the form of wage index manipulation we addressed in the proposed rule was not limited to any specific hospital type. Therefore, we believe it is appropriate to apply it to all hospitals with rural reclassification status. We believe the proposed policy of requiring that rural reclassification be in effect for at least 1 year before cancellation can be requested, and the proposed policy to make rural reclassification cancellations effective beginning the Federal fiscal year that begins in the calendar year after the calendar year in which the cancellation request is submitted will reduce the instances of wage index manipulation described previously, as well as reduce volatility and promote accuracy in overall wage index values by ensuring that hospitals that are being paid a State's rural wage index are eventually included, when applicable, in that rural wage index calculation. We note that this form of manipulation (hospitals canceling rural status to remove their wage data from the rural wage index calculation) resulted in the rural wage index for one state increasing by over 4 percent between the FY 2020 proposed rule and the FY 2020 final rule. Based on our analysis, that figure could have been significantly greater (as high as 10 percent) in certain States. We further believe these proposed policies provide adequate time for hospitals to review their reclassification status and make appropriate decisions for future fiscal years. Hospitals that meet the proposed 1-year minimum requirement in proposed § 412.103(g)(4) would have opportunity between the publication date of the final rule (and potential correction notices) and the end of the calendar year to evaluate whether to cancel or maintain their rural status for the next fiscal year.

Comment: We received a comment stating strong support for CMS' actions to prevent hospitals from using 412.103 as a mechanism for statewide wage index manipulation. However, the commenter requested that this policy be limited only to hospitals that obtained rural reclassification after October 1, 2020. The commenter stated that CMS should allow hospitals with longstanding rural reclassification status to maintain an appropriate level of flexibility while appropriately restricting cancellations for hospitals that may engage in the form of wage index manipulation discussed in the proposed rule. Other commenters, while acknowledging CMS' policy motivations, suggested alternative revisions to the rural reclassification cancellation policy to avoid unfairly penalizing hospitals that are not motivated by the form of wage index manipulation discussed in the proposed rule. Specifically, a commenter requested CMS, rather than further limit a hospital's ability to cancel rural reclassification status, instead limit a hospital's ability to reapply for rural reclassification for a period of time following an approved for cancellation.

Another commenter requested CMS exclude hospitals from the proposed cancellation policies if they meet a variety of conditions that would indicate they are not attempting to obtain their State's rural wage index while avoiding the inclusion of their hospital's data in the wage index calculations. This commenter stated the

[758] ''Lugar'' hospitals may reclassify as rural and retain the urban wage index deemed under section 1886(d)(8)(B) of the Act, as discussed in the FY 2017 IPPS/LTCH final rule (81 FR 56929).

proposed policies were too onerous, and should be modified to specifically target the behavior that CMS is addressing. The commenter also recommended excluding hospitals that maintained rural reclassification status for at least 2 consecutive years from the newly imposed restrictions of the proposed cancellation policy, and also suggested CMS explore a policy of making mid-year corrections to wage index values to ensure that hospitals that obtain rural reclassifications have their data included in its State's rural wage index calculations.

Response: We appreciate the input from commenters. We believe that the comments received were generally supportive of CMS' action to limit the ability for hospitals to time rural reclassification and cancellations in order to receive a higher rural wage index without having their own data included in the rural wage index calculation. We have reviewed and taken into consideration the suggested modifications to our proposed policies. Certain suggestions, such as limiting a hospital's ability to reapply for rural reclassification status after recently cancelling a prior rural reclassification, may not be consistent with the statutory requirements regarding the effective date and approval criteria for rural reclassification applications. In our proposal to require a cancellation be submitted in the calendar year prior to the fiscal year it would become effective, we acknowledged this would add a significant amount of time to the current requirement at § 412.103(g)(3). Currently, a cancellation request must be submitted at least 120 days prior to the end of a fiscal year to be effective for the upcoming fiscal year. Under our proposal, requests must be submitted approximately 152 days earlier (by December 31st). We understand that hospitals wish to have an opportunity to review data in the proposed rule to determine whether to maintain or cancel any particular reclassification status, including rural reclassifications under section § 412.103. However, as discussed in the proposed rule (86 FR 25412) there may exist the potential for wage index manipulation by timing cancellation requests and new applications around the ''lock-in'' date and the current 120 day deadline to submit rural reclassification cancellation requests. We proposed the policy of requiring rural reclassification cancellation requests to be submitted in the calendar year prior to the fiscal year it would become effective. However, if finalized, our proposal to require rural reclassification be held for one full year would mean that any hospital that requested cancellation effective for FY 2022 (that is, submitted a cancellation request on or before the June 2, 2021 deadline), and reapplied for rural reclassification after October 1, 2021, would not be eligible to cancel that new reclassification status until FY 2024 at the earliest, reducing the urgency to implement the additional revisions to the cancellation policy in FY 2022.

In response to comments received, we believe it would be appropriate to delay and potentially revise our proposal to require cancellation requests be effective for the Federal fiscal year that begins in the calendar year after the calendar year in which the cancelation request is submitted in order to assure the policy effectively targets the form of wage index manipulation discussed previously.

The current policy of requiring cancellation requests be submitted not less than 120 day prior to the end of the Federal fiscal year will remain in place while we evaluate alternative methods to obtain our policy goals. However, to address the potential for rural wage index manipulation in FY 2022 and future years, we are finalizing the proposed policy that rural reclassification be in effect for at least 1 year before cancellation can be requested. Specifically, we are adding § 412.103(g)(4) to state that for all written requests submitted by hospitals on or after October, 1, 2021 to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 1 calendar year after the effective date of the rural reclassification and not less than 120 days prior to the end of a Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year. We believe this policy will not affect hospitals with longstanding rural reclassification status, would not unduly burden hospitals that obtained rural reclassification status for reasons not involving the rural wage index calculations, and will effectively address the wage index manipulation issue in the upcoming fiscal years.

We will continue to monitor rural reclassification applications and cancellation requests. We will take into consideration the comments we have so far received and, if necessary, make additional proposals to address this issue further in future fiscal years.

3. Finalization of Interim Final Rule With Comment Period on Provisions Related To Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board Interim Final Rule (CMS–1762–IFC)

In the interim final rule with comment period (IFC) (CMS–1762–IFC) simultaneously submitted for public inspection with the proposed rule, CMS made regulatory changes in order to align our policy with the decision in *Bates.* Specifically, the IFC revised the regulations at § 412.230 to allow hospitals with a rural redesignation under section 1886(d)(8)(E) of the Act to reclassify under the MGCRB using the rural reclassified area as the geographic area in which the hospital is located effective with reclassifications beginning with FY 2023. We stated we would also apply the policy in the IFC when deciding timely appeals before the Administrator of applications for reclassifications beginning with FY 2022 that were denied by the MGCRB due to the policy in effect prior to the IFC, which did not permit hospitals with rural redesignations to use the rural area's wage data for purposes of reclassifying under the MGCRB. In this section of this final rule, we are responding to the public comments that we received on these provisions in the May 10, 2021 IFC and finalizing the interim policies.

a. Background

i. Wage Index for Acute Care Hospitals Paid Under the Hospital Inpatient Prospective Payment System (IPPS)

Under section 1886(d) of the Social Security Act (the Act), hospitals are paid based on prospectively set rates. To account for geographic area wage level differences, section 1886(d)(3)(E) of the Act requires that the Secretary of the Department of Health and Human Services (the Secretary) adjust the standardized amounts by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital, as compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01, with updates as reflected in OMB Bulletins Nos. 15–01, 17–01, and 18–04. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full

discussion of our implementation of the new OMB labor market area delineations beginning with the FY 2015 wage index, and to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) for a discussion of the latest updates to these delineations.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index of hospitals annually, and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS, after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act, regarding geographic reclassification of hospitals, are equal to the aggregate prospective payments that would have been made absent these provisions.

ii. Hospital Reclassifications Under Sections 1886(d)(8)(E) and 1886(d)(10) of the Act

Hospitals may seek to have their geographic designation reclassified. Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status. Specifically, section 1886(d)(8)(E) of the Act states that ''[f]or purposes of this subsection, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital described in clause (ii), the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the state in which the hospital is located.'' The regulations governing these geographic redesignations are codified in § 412.103, and such hospitals are therefore commonly referred to as ''§ 412.103 hospitals.''

In a separate process, hospitals may also reclassify for purposes of the wage index under the IPPS under section 1886(d)(10) of the Act by applying to the Medicare Geographic Classification Review Board (MGCRB). Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought, generally by September 1. (However, we note that this deadline has been extended for applications for FY 2022 reclassifications to 15 days after the public display date of the FY 2021 IPPS/LTCH final rule at the Office of the Federal Register, using our authority under section 1135(b)(5) the Act due to the COVID–19 Public Health Emergency.) Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in §§ 412.230 through 412.280.

Prior to a court decision in *Geisinger Community Medical* v. *Secretary, United States Department of Health and Human Services,* 794 F.3d 383 (3d Cir. 2015) *(''Geisinger''),* hospitals were only able to hold one reclassification at a time: Either under § 412.103 or through the MGCRB under section 1886(d)(10) of the Act. The Court of Appeals in *Geisinger* ruled that CMS' prohibition of dual § 412.103 and MGCRB reclassifications was unlawful, since section 1886(d)(8)(E)(i) of the Act requires that ''the Secretary shall treat the hospital as being located in the rural area,'' inclusive of MGCRB reclassification purposes. Therefore, on April 21, 2016, we published an interim final rule with comment period (the April 21, 2016 IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications.

b. Provisions of the Interim Final Rule With Comment Period

Pursuant to our April 21, 2016 IFC, for reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using the distance and average hourly wage criteria designated for rural hospitals. Hospitals with a § 412.103 redesignation seeking additional reclassification under the MGCRB use the rural distance and average hourly wage criteria under § 412.230(b)(1), (d)(1)(iii)(C), and (d)(1)(iv)(E). For example, under our policy prior to the issuance of the May 10, 2021 IFC, a § 412.103 hospital geographically located in the urban CBSA of Buffalo-Cheektowaga, NY seeking to reclassify under the MGCRB would demonstrate that their wages are at least 106 percent (and not 108 percent, as urban hospitals must demonstrate) of the average hourly wage of Buffalo-Cheektowaga, NY, to meet the criteria at § 412.230(d)(1)(iii)(C).

However, our policy prior to the issuance of the May 10, 2021 IFC compared the average hourly wage of a § 412.103 hospital to its geographic urban location, rather than the rural reclassified area, for purposes of satisfying certain wage comparison criteria. In response to a comment on our April 21, 2016 IFC (81 FR 56925), we stated: ''The commenter is correct that the rural distance and average hourly wage criteria will be used for hospitals with a § 412.103 redesignation. However, the commenter's statement that the average hourly wage of a hospital with a § 412.103 redesignation is compared to the average hourly wage of hospitals in the State's rural area under § 412.230(d)(1)(iii)(C) is incorrect. Instead, the hospital's average hourly wage would be compared to the average hourly wage of all other hospitals in its urban geographic location using the rural distance and average hourly wage criteria.''

On May 14, 2020, the United States District Court for the District of Columbia issued a decision in *Bates.* Bates County Memorial Hospital and five other geographically urban hospitals were reclassified to rural under § 412.103. They also applied for reclassification under the MGCRB, but were denied because their wages were not at least 106 percent of the geographic urban area in which the hospitals were located. Each of the hospitals' average hourly wages were at least 106 percent of the 3-year average hourly wage of all other hospitals in the rural area of the state in which the hospitals are located.

The court agreed with the Plaintiffs that the statute at section 1886(d)(8)(E)(i) of Act requires that CMS treat qualifying hospitals as being located in the rural area for purposes of section 1886(d) of the Act, including MGCRB reclassification. The *Bates* decision requires that CMS consider the rural area to be the area in which the hospital is located for the wage comparisons required for MGCRB reclassifications. For example, pursuant to *Bates,* a § 412.103 hospital geographically located in the urban CBSA of Buffalo-Cheektowaga, NY seeking to reclassify under the MGCRB would demonstrate that their wages are at least 106 percent of the average hourly wage of rural NY, rather than that of Buffalo-Cheektowaga.

As a result of the *Bates* court's decision, we revised our policy in the May 10, 2021 IFC so that the redesignated rural area, and not the hospital's geographic urban area, are considered the area a § 412.103 hospital is located in for purposes of meeting MGCRB reclassification criteria. Similarly, we revised the regulations to consider the redesignated rural area, and not the geographic urban area, as

the area a § 412.103 hospital is located in for the prohibition at § 412.230(a)(5)(i) on reclassifying to an area with a pre-reclassified average hourly wage lower than the pre-reclassified average hourly wage for the area in which the hospital is located.

Specifically, to align our policy with the court's decision in *Bates,* we amended the regulations at § 412.230(a)(1) by adding (a)(1)(iii) to state that an urban hospital that has been granted redesignation as rural under § 412.103 is considered to be located in the rural area of the state for the purposes of this section. We also made conforming changes to the regulation at § 412.230(a)(5)(i) because § 412.230(a)(1) excepts paragraph (a)(5). Because § 412.230(a)(1) excepts paragraph (a)(5), we believed it was necessary to make a specific conforming revision to § 412.230(a)(5)(i), in addition to the general rule at § 412.230(a)(1)(iii), to clarify that the general rule at § 412.230(a)(1)(iii) applies to § 412.230(a)(5)(i) as well. That is, we amended the regulation at § 412.230(a)(5)(i) to add language stating that an urban hospital that has been granted redesignation as rural under § 412.103 is considered to be located in the rural area of the state for the purposes of paragraph (a)(5)(i).

These changes implemented the *Bates* court's interpretation of the requirement at section 1886(d)(8)(E)(i) of the Act that ''the Secretary shall treat the hospital as being located in the rural area.'' That is, effective with our in the May 10, 2021 IFC, a § 412.103 hospital would be considered to be located in the rural area of the state for all purposes of MGCRB reclassification, including the average hourly wage comparisons required by § 412.230(a)(5)(i) and (d)(1)(iii)(C). For example, for purposes of § 412.230(d)(1)(iii)(C), the § 412.103 hospital compares its average hourly wage to the average hourly wage of all other hospitals in the state's rural area. In addition, for purposes of § 412.230(a)(5)(i), a § 412.103 hospital may not be redesignated to another area if the pre-classified average hourly wage for that area is lower than the pre-reclassified average hourly wage of the rural area of the state in which the hospital is located (thus, a § 412.103 hospital could potentially reclassify to any area with a pre-reclassified average hourly wage that is higher than the pre-reclassified average hourly wage for the rural area of the state, if it meets all other applicable reclassification criteria).

Therefore, effective for reclassification applications due to the MGCRB on September 1, 2021, for reclassification first effective for FY 2023, a § 412.103 hospital could apply for a reclassification under the MGCRB using the state's rural area as the area in which the hospital is located. We stated in the May 10, 2021 IFC that we would also apply the policy when deciding timely appeals before the Administrator under § 412.278 for reclassifications beginning in FY 2022 that were denied by the MGCRB due to existing policy, which did not permit § 412.103 hospitals to be considered located in the state's rural area.

Comment: We received comments in support of our IFC modifying limitations on redesignation by the MGCRB. A commenter requested clarification regarding the CBSA column typically included in the Three Year MGCRB Reclassification Data File that is released in August each year. The commenter questioned if the CBSA column for hospitals with a § 412.103 reclassification will reflect the redesignated rural CBSA that would now be used when determining if a hospital meets the MGCRB reclassification criteria, or the hospital's geographic urban CBSA. Similarly, another commenter questioned if the § 412.103 hospital applying for MGCRB reclassification should include other § 412.103 hospitals in the rural average hourly wage for this regulation for purposes of the home area wage test at § 412.230(d)(1)(iii)(C). This commenter suggested that CMS should require hospitals to compare their average hourly wage against the average hourly wage calculated only for those hospitals actually located in the rural area, exclusive of hospitals with 412.103 rural redesignations, for simplicity of applying this policy. The commenter explained that because hospitals can obtain § 412.103 rural redesignation at any time, it may not be clear at the time the MGCRB is reviewing reclassification applications which hospitals have obtained § 412.103 rural reclassifications since the publication of the most recent IPPS tables.

Response: We thank the commenters for their support. In response to the commenter's question regarding which CBSA will be published in the Three Year MGCRB Reclassification Data File used for MGCRB reclassification, we are clarifying that the hospital's geographic urban CBSA will continue to be listed. Therefore, a § 412.103 hospital applying for MGCRB reclassification would not include other § 412.103 hospitals in the rural average hourly wage for this regulation for purposes of the home area wage test at § 412.230(d)(1)(iii)(C). For the reasons the second commenter suggested, we believe this is the most clear and straightforward application of this policy to implement the court's decision in *Bates.* If we were to require that the wages and hours of all hospitals with § 412.103 reclassifications be included in the rural area for purposes of the home area wage test, we would need to list the rural CBSA as the geographic CBSA for hospitals with § 412.103 reclassifications in the Three Year MGCRB Reclassification Data File. However, as the second commenter noted, since § 412.103 reclassifications may be obtained at any time, it would not be clear if the Three Year MGCRB Reclassification Data File accurately captures all hospitals with § 412.103 reclassifications.

Comment: A commenter noted that the IFC states that a hospital reclassified under § 412.103 could potentially reclassify to any area with a prereclassified average hourly wage that is higher than the pre-reclassified average hourly wage for the rural area of the state for purposes of the regulation at § 412.230(a)(5)(i). The commenter asserted that CMS' use of the word ''could'' in this context seems to suggest that CMS would allow the hospital to use either its home average hourly wage or the rural average hourly wage for purposes of the regulation at § 412.230(a)(5)(i). The commenter suggested that CMS allow both comparison options, because the rural average hourly wage may occasionally be higher than the hospital's home urban area's average hourly wage, such as in the state of Massachusetts.

Response: The commenter's interpretation of our policy is correct. While the court's decision in *Bates* requires CMS to permit hospitals to reclassify to any area with a prereclassified average hourly wage that is higher than the pre-reclassified average hourly wage for the rural area of the state, we do not believe that we are required to limit hospitals from using their geographic home area for purposes of the regulation at § 412.230(a)(5)(i). Therefore, we are clarifying that we would allow hospitals to reclassify to an area with an average hourly wage that is higher than the average hourly wage of either the hospital's geographic home area or the rural area.

Comment: A commenter questioned whether a hospital reclassified under § 412.103 should include its own wage data and the wage data of other hospitals reclassified under § 412.103 in determining the rural average hourly wage for purposes of the regulation at § 412.230(a)(5)(i). The commenter suggested that CMS not require this, since including hospitals reclassified under § 412.103 in the rural average

hourly wage would change the average hourly wage from the published value in the final rule tables. Accordingly, the commenter requested that CMS not include hospitals reclassified under § 412.103 in the rural average hourly wage for § 412.230(a)(5)(i) for simplicity in applying this policy.

Response: We agree with the commenter. In calculating the rural area's average hourly wage for purposes of applying § 412.230(a)(5)(i), we are clarifying that we are not requiring hospitals to include the wage data of hospitals with § 412.103 rural reclassifications. For the reasons the commenter stated, we believe this is the simplest and most clear application of the policy the court required in *Bates.*

In this final rule, we are finalizing the provisions of the May 10, 2021 IFC without modification, including our revisions to the regulations at § 412.230 to allow hospitals with a rural redesignation under section 1886(d)(8)(E) of the Act to reclassify under the MGCRB using the rural reclassified area as the geographic area in which the hospital is located effective with reclassifications beginning with FY 2023.

L. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2022 wage index were made available on May 18, 2020 and the preliminary CY 2019 occupational mix data files for the proposed FY 2022 wage index were made available on September 8, 2020 through the internet on the CMS website at: *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page.*

On January 29, 2021, we posted a public use file (PUF) at: *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page* containing FY 2022 wage index data available as of January 28, 2021. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2017 through September 30, 2018; that is, FY 2018 wage data), a tab with the occupational mix data (which includes data from the CY 2019 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 29, 2021 wage data PUF, and a tab containing the CY 2019 occupational mix data of the hospitals deleted from the January 29, 2021 occupational mix PUF. In a memorandum dated January 22, 2021, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 29, 2021 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2022 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at: *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums*.

In a memorandum dated April 14, 2020, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files posted on May 18, 2020, the requirement to submit the new CY 2019 occupational mix surveys by August 3, 2020 and the process and timeframe for requesting revisions. Subsequently, in a memorandum dated July 31, 2020, we revised the date hospitals were required to submit the new CY 2019 occupational mix surveys from August 3, 2020 to September 3, 2020, the date the preliminary CY 2019 occupational mix survey data files were scheduled to be posted from August 6, 2020 to September 8, 2020 and the timeframe for requesting revisions to the new CY 2019 occupational mix survey data.

If a hospital wished to request a change to its data as shown in the May 18, 2020 preliminary wage data files (or September 8 2020 preliminary CY 2019 occupational mix survey data files), the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 3, 2020 (or by September 10, 2020 for preliminary CY 2019 occupational mix survey data files). Hospitals were notified of these deadlines and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs. November 16, 2020 was the deadline for MACs to complete all desk reviews for hospital wage and occupational mix data and transmit revised Worksheet S–3 wage data and occupational mix data to CMS.

November 5, 2020 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2021. CMS published the wage index PUFs that included hospitals' revised wage index data on January 29, 2021. Hospitals had until February 16, 2021, to submit requests to the MACs to correct errors in the January 29, 2021 PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 29, 2021 PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must be received by the MAC by the February deadline (that is, by February 16, 2021 for the FY 2021 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 19, 2021. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 2, 2021. Data that were incorrect in the preliminary or January 29, 2021 wage index data PUFs, but for which no correction request was received by the February 16, 2021 deadline, are not considered for correction at this stage. In addition, April 2, 2021 was the deadline for hospitals to dispute data corrections de by CMS of which the hospital was notified after the January 29, 2021 PUF and at least 14 calendar days prior to April 2, 2021 (that is, March 19, 2021), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 2, 2021 for the FY 2022 wage index). We refer readers to the wage index timeline for complete details.

Hospitals were given the opportunity to examine Table 2 associated with the proposed rule, which is listed in section VI. of the Addendum to the proposed

rule and available via the internet on the CMS website at: *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-proposed-rule-home-page*. Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the proposed FY 2022 wage index which was constructed from FY 2018 data. We noted in the proposed rule that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by early February 2021.

We posted the final wage index data PUFs on April 30, 2021 on the CMS website at: *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page*. The April 2021 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (the process for disputing revisions submitted to CMS by the MACs by March 19, 2021, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier).

After the release of the April 2021 wage index data PUFs, changes to the wage and occupational mix data could only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 19, 2021.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 29, 2021 wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2021 final wage index data PUFs, a hospital believed that its wage or occupational mix data were incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital was given the opportunity to notify both its MAC and CMS regarding why the hospital believed an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital was required to send its request to CMS and to the MAC so that it was received no later than May 28, 2021. May 28, 2021 was also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified on or after 13 calendar days prior to April 2, 2021 (that is, March 20, 2021), and at least 14 calendar days prior to May 28, 2021 (that is, May 14, 2021), that did not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital was notified on or after 13 calendar days prior to May 28, 2021 (that is, May 15, 2021) may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2022 wage index timeline posted on the CMS website at: *https://www.cms.gov/files/document/fy-2022-hospital-wage-index-development-time-table.pdf*, the May appeals were required to be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely (that is, by May 28, 2021) by CMS and the MACs were incorporated into the final FY 2022 wage index, which will be effective October 1, 2021.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2022 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2021, they have an opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2022 wage index by August 2021, and the implementation of the FY 2022 wage index on October 1, 2021. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 28, 2021, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 28, 2021 for the FY 2022 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 28, 2021 deadline for the FY 2022 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 28, 2021 deadline for the FY 2022 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the January 29 Public Use File (PUF)

The process set forth with the wage index timeline discussed in section III.L.1. of the preamble of this final rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 29 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 29 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting review of such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency to instances where CMS makes data corrections after the January 29 PUF, and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2022 Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

M. Labor-Related Share for the FY 2022 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we rebased and revised the hospital market basket. We established a 2014-based IPPS hospital market basket to replace the FY 2010-based IPPS hospital market basket, effective October 1, 2017. Using the 2014-based IPPS market basket, we finalized a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017. In addition, in FY 2018, we implemented this revised and rebased labor-related share in a budget neutral manner (82 FR 38522). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58793), for FY 2021, we continued to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2020.

For FY 2022, as described in section IV. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25416 through 25417), we proposed to rebase and revise the IPPS market basket reflecting 2018 data. We also proposed to recalculate the labor-related share for discharges occurring on or after October 1, 2021 using the proposed 2018-based IPPS market basket. As discussed in Appendix A of the proposed rule, we proposed this rebased and revised labor related share in a budget neutral manner. However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000. We refer readers to section IV. of the preamble of this final rule and Appendix A for our finalized policies for the 2018-based IPPS market basket.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. As described in section IV. of the preamble of the proposed rule, beginning with FY 2022, we proposed to include in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the proposed 2018-based IPPS market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other Labor-Related Services, as measured in the proposed 2018-based IPPS market basket. Therefore, for FY 2022, we proposed to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021.

We refer readers to section IV.B.3. of the preamble of this final rule for a discussion of our recalculation of the labor-related share for discharges occurring on or after October 1, 2021 using the 2018-based IPPS market basket.

As discussed in section V.B. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2022, we did not propose a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Comment: A commenter stated that if CMS determines that a reduction in the labor-related share is supported by data and appropriate for either Professional Services Fees or Home Office/Related Organization cost weight categories, they requested that—similar to other wage index related changes—CMS phase in a reduction of the labor-related share. The commenter requested that any phase-in be over a period of three years and implemented in a non-budget-neutral manner in recognition of hospital finances in the wake of the COVID–19 PHE.

Response: As noted earlier, section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. In section IV.B.3. of the preamble of this final rule, we discuss our recalculation

of the labor-related share for discharges occurring on or after October 1, 2021, using the 2018-based IPPS market basket. We believe that the labor-related share calculated for FY 2022 accurately and appropriately reflects the proportion of hospitals' costs that are attributable to wages and wage-related costs. Therefore, we do not believe it is necessary or appropriate to phase in the effects of the labor-related share percentage finalized in this rule. After consideration of the public comments we received, for the reasons discussed in section IV.B.3. of the preamble of this final rule and in the FY 2022 IPPS/LTCH PPS proposed rule, we are finalizing our proposal to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021, for all hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.0000.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2022 IPPS/LTCH PPS final rule and available via the internet on the CMS website, reflect the national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2022, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2022, we are applying the wage index to the labor-related share of 67.6 percent of the national standardized amount.

IV. Rebasing and Revising of the Hospital Market Baskets for Acute Care Hospitals

A. Background

Effective for cost reporting periods beginning on or after July 1, 1979, we developed and adopted a hospital input price index (that is, the hospital market basket for operating costs). Although ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket'' as used in this document refers to the hospital input price index.

The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase in order to provide inpatient care. We first used the market basket to adjust hospital cost limits by an amount that reflected the average increase in the prices of the goods and services used to provide hospital inpatient care. This approach linked the increase in the cost limits to the efficient utilization of resources.

Since the inception of the IPPS, the projected change in the hospital market basket has been the integral component of the update factor by which the prospective payment rates are updated every year. An explanation of the hospital market basket used to develop the prospective payment rates was published in the **Federal Register** on September 1, 1983 (48 FR 39764). We also refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175) in which we discussed the most recent previous rebasing of the hospital input price index.

The hospital market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in the proposed rule, we proposed to use 2018 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, and the proportion of total costs that each category represents are calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

We last rebased the hospital market basket cost weights effective for FY 2018 (82 FR 38158 through 38175), with 2014 data used as the base period for the construction of the market basket cost weights. For the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to rebase the IPPS operating market basket to reflect the 2018 cost structure for IPPS hospitals and to revise applicable cost categories and price proxies used to determine the IPPS market basket, as discussed in this final rule. We also proposed to rebase and revise the Capital Input Price Index (CIPI) as described in section IV.D. of the preamble of this final rule.

B. Rebasing and Revising the IPPS Market Basket

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. ''Rebasing'' means moving the base year for the structure of costs of an input price index (for example, in the proposed rule, we proposed to shift the base year cost structure for the IPPS hospital index from 2014 to 2018). ''Revising'' means changing data sources or price proxies used in the input price index. As published in the FY 2006 IPPS final rule (70 FR 47403), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket. We established a rebasing frequency of every 4 years and, therefore, for the FY 2022 IPPS update, we proposed to rebase and revise the IPPS market basket from 2014 to 2018. We invited public comments on our proposed methodology.

Comment: A few commenters supported the rebasing of the market basket. A commenter stated they were in agreement to utilize 2018 data for the

rebased market basket. A commenter stated that they appreciated the update of the market basket from 2014 to 2018 as well as the update of the labor-related share.

Response: We appreciate the commenters' support to rebase and revise the IPPS market basket from a 2014 base year to a 2018 base year. We note that we proposed to use the rebased and revised market baskets for FY 2022 in compliance with section 404 of the MMA, which required us to established a frequency for updating the IPPS market basket cost weights and labor-related share. In compliance with that statute, we established a frequency of every 4 years (70 FR 47403). We last rebased the hospital market basket cost weights effective for FY 2018 (82 FR 38158 through 38175), with 2014 data used as the base period for the construction of the market basket cost weights.

1. Development of Cost Categories and Weights

a. Use of Medicare Cost Report Data

The major source of expenditure data for developing the proposed rebased and revised hospital market basket cost weights is the 2018 Medicare cost reports. These 2018 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2017 and before October 1, 2018. We proposed to use 2018 as the base year because we believe that the 2018 Medicare cost reports represent the most recent, complete set of Medicare cost report data available to develop cost weights for IPPS hospitals at the time of rulemaking. We believe it is important to regularly rebase and revise the IPPS market basket to reflect more recent data. Historically, the cost weights change minimally from year to year as they represent percent of total operating costs rather than cost levels; however, given the COVID–19 public health emergency we will continue to monitor the upcoming Medicare cost report data to see if a more frequent rebasing schedule is necessary than our current schedule of every 4 years. As was done in previous rebasings, these cost reports are from IPPS hospitals only (hospitals excluded from the IPPS and CAHs are not included) and are based on IPPS Medicare-allowable operating costs. IPPS Medicare-allowable operating costs are costs that are eligible to be paid under the IPPS. For example, the IPPS market basket excludes home health agency (HHA) costs as these costs would be paid under the HHA PPS and, therefore, these costs are not IPPS Medicare-allowable costs.

The current set of instructions for the Medicare cost reports for hospitals (Form 2552–10, OMB Control Number 0938–0050) can be found in Chapter 40 at the following website (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, accessed February 17, 2021). As described in these instructions, effective for cost reporting periods beginning on or after October 1, 2015, Worksheet S–3, Part II was revised to add lines 14.01, 14.02, 25.50, 25.51, 25.52, and 25.53, to enhance the wage index data collection. This modification was made for Transmittal 10 and is specifically highlighted in the instructions, which can be found at the following website: (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R10P240.pdf*, accessed February 17, 2021). Therefore, as noted later in this section, for the 2018-based IPPS market basket, we proposed to use these more detailed lines for the development of the market basket cost categories. These detailed lines were not available at the time we finalized the 2014-based IPPS market basket.

We proposed to derive costs for eight major expenditures or cost categories for the 2018-based IPPS market basket from the CMS Medicare cost reports (Form 2552–10, OMB Control Number 0938–0050): Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (Malpractice), Blood and Blood Products, Home Office/Related Organization Contract Labor, and a residual ''All Other'' category. The residual ''All Other'' category reflects all remaining costs that are not captured in the other seven cost categories. These are the same major cost categories from the Medicare cost reports that were derived for the 2014-based IPPS market basket. In this rule, we describe the detailed methodology for obtaining costs for each of the seven cost categories directly determined from the Medicare cost reports.

In order to create a market basket that is representative of IPPS hospitals serving Medicare patients and to help ensure accurate major cost weights (which is the percent of total Medicare-allowable operating costs, as defined in this final rule), we proposed to apply edits to remove reporting errors and outliers. Specifically, the IPPS Medicare cost reports used to calculate the market basket cost weights exclude any providers that reported costs less than or equal to zero for the following categories: Total Medicare inpatient costs (Worksheet D, Part I, column 1, line 49); Medicare PPS payments (Worksheet E, Part A, column 1, line 59); Total salary costs (Worksheet S–3, Part II, column 2, line 1). We also limited our sample to providers that had a Medicare cost reporting period that was between 10 and 14 months. The final sample used included roughly 3,200 Medicare cost reports (about 94 percent of the universe of IPPS Medicare cost reports for 2018). The sample of providers is representative of the national universe of providers by ownership-type (proprietary, nonprofit, and government) and by urban/rural status.

First, we proposed to calculate total Medicare-allowable operating costs for each hospital. We proposed that total Medicare-allowable operating costs are equal to noncapital costs (Worksheet B, Part I, column 26 less Worksheet B, Part II, column 26) that are attributable to the Medicare-allowable cost centers of the hospital. We proposed that Medicare-allowable cost centers are lines 30 through 35, 50 through 60, 62 through 76, 90, 91, 92.01, 93, 96 and 97. This is the same general methodology that was used for the 2014-based IPPS market basket. However, we note that for the development of the 2018-based IPPS market basket, we conducted a detailed review of the cost centers and now proposed to include lines 52, 96, and 97 when deriving total Medicare-allowable operating costs as these reflect Medicare-allowable services that are reimbursed under the IPPS.

(1) Wages and Salaries Costs

To derive wages and salaries costs for the Medicare-allowable cost centers, we proposed to first calculate total unadjusted wages and salaries costs as reported on Worksheet S–3, Part II, column 4, line 1. We then proposed to remove the wages and salaries attributable to non-Medicare-allowable cost centers (that is, excluded areas) as well as a portion of overhead wages and salaries attributable to these excluded areas. This is the same general methodology that was used to derive wages and salaries costs for the 2014-based IPPS market basket. However, we note that we proposed minor changes to the Medicare cost report lines that are used to derive excluded area wages and salaries as well as overhead wages and salaries attributable to these areas as described in this rule as we believe these represent a technical improvement to the Medicare cost report lines used for the 2014-based IPPS market basket. The description of the detailed methodology used for the 2014-based IPPS market basket was provided in the FY 2018 IPPS/LTCH final rule (82 FR 38159).

Specifically, we proposed to calculate excluded area wages and salaries as equal to the sum of Worksheet S–3, Part II, column 4, lines 3, 4.01, 5, 6, 7, 7.01, 8, 9, and 10 less Worksheet A, column 1, lines 20 and 23. Overhead wages and salaries are attributable to the entire IPPS facility. Therefore, we proposed to only include the proportion attributable to the Medicare-allowable cost centers. Specifically, we proposed to estimate the proportion of overhead wages and salaries that are not attributable to Medicare-allowable costs centers (that is, excluded areas) by first calculating the ratio of total Medicare-allowable operating costs as previously defined to total facility operating costs (Worksheet B, Part I, column 26, line 202 less Worksheet B, Part I, column 0, lines 1 and 2). We then proposed to multiply this ratio by total overhead wages and salaries (Worksheet S–3, Part II, column 4, lines 26, 27, 29 through 32, 34, and 36 through 43).

Therefore, the proposed wages and salaries costs are equal to total wages and salaries costs less: (a) Excluded area wages and salaries costs; and (b) overhead wages and salaries costs attributable to the excluded areas.

(2) Employee Benefits Costs

We proposed to derive employee benefits costs using a similar methodology as the wages and salaries costs; that is, reflecting employee benefits costs attributable to the Medicare-allowable cost centers. First, we calculate total unadjusted employee benefits costs as the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 20, 22, and 25.52. The 2014-based IPPS market basket used Worksheet S–3, Part II, column 4, lines 17, 18, 20 and 22 to derive the costs for this category. As described previously, line 25.52 reflects a newly added line to Worksheet S–3, Part II since the development of the 2014-based IPPS market basket.

We then exclude those employee benefits attributable to the overhead wages and salaries for the non-Medicare-allowable cost centers (that is, the excluded areas). Employee benefits attributable to the non-Medicare-allowable cost centers are derived by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 19, 20, 21, 22, 22.01, 23, 24, 25, 25.50, 25.51, 25.52, and 25.53) to total wages and salaries (Worksheet S–3, Part II, column 4, line 1) by excluded overhead wages and salaries (as previously described in section IV.B.1.a.(1). of the preamble of this final rule for wages and salaries costs). A similar methodology was used in the 2014-based IPPS market basket.

(3) Contract Labor Costs

Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described in this final rule. We proposed to derive contract labor costs for the 2018-based IPPS market basket as the sum of Worksheet S–3, Part II, column 4, lines 11, 13, and 15. A similar methodology was used in the 2014-based IPPS market basket.

(4) Professional Liability Insurance Costs

We proposed that professional liability insurance (PLI) costs (often referred to as malpractice costs) be equal to premiums, paid losses, and self-insurance costs reported on Worksheet S–2, Part I, columns 1 through 3, line 118.01. A similar methodology was used for the 2014-based IPPS market basket.

(5) Pharmaceuticals Costs

We proposed to calculate pharmaceuticals costs as total costs reported for the Pharmacy cost center (Worksheet B, Part I, column 0, line 15) and Drugs Charged to Patients cost center (Worksheet B, Part I, column 0, line 73) less wages and salaries attributable to these two cost centers (Worksheet S–3, Part II, column 4, line 40 and Worksheet A, column 1, line 73) less estimated employee benefits attributable to these two cost centers. We proposed to estimate the employee benefits costs by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 19, 20, 21, 22, 22.01, 23, 24, 25, 25.50, 25.51, 25.52, and 25.53) to total wages and salaries (Worksheet S–3, Part II, column 4, line 1) by total wages and salaries costs for the Pharmacy and Drugs Charged to Patients cost centers (equal to the sum of Worksheet S–3, Part II, column 4, line 40 and Worksheet A, column 1, line 73). The same general methodology was used for the 2014-based IPPS market basket. However, we note that for the 2014-based IPPS market basket, for calculating the total nonsalary costs we used Worksheet A, column 2 for each cost center instead of our proposed method of using Worksheet B, Part I, column 0, less salary costs. We proposed to use Worksheet B, Part I, column 0 as this would reflect reclassifications and adjustments (which are made on columns subsequent to Worksheet A columns 1 and 2).

(6) Blood and Blood Products Costs

We proposed to calculate blood and blood products costs as total costs reported for the Whole Blood & Packed Red Blood Cells cost center (Worksheet B, Part I, column 0, line 62) and the Blood Storing, Processing, & Transfusing cost center (Worksheet B, Part I, column 0, Line 63) less wages and salaries attributable to these two cost centers (Worksheet A, column 1, lines 62 and 63) less estimated employee benefits attributable to these two cost centers. We estimate these employee benefits costs by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 19, 20, 21, 22, 22.01, 23, 24, 25, 25.50, 25.51, 25.52, and 25.53) to total wages and salaries (Worksheet S–3, Part II, column 4, line 1) by total wages and salaries for the Whole Blood & Packed Red Blood Cells and Blood Storing, Processing, & Transfusing cost centers (equal to the sum of Worksheet A, Column 1, lines 62 and 63). The same general methodology was used for the 2014-based IPPS market basket. However, we note that for the 2014-based IPPS market basket, for calculating the total nonsalary costs we used Worksheet A, column 2 for lines 62 and 63 instead of our proposed method of using Worksheet B, Part I, column 0, lines 62 and 63, less salary costs. Similar to our proposed method for Pharmaceuticals costs, we proposed to use Worksheet B, Part I, column 0 as this would reflect reclassifications and adjustments (which are made on columns subsequent to Worksheet A columns 1 and 2).

(7) Home Office Contract Labor/Related Organization Costs

We proposed to determine home office/related organization contract labor costs using data reported on Worksheet S–3, Part II, column 4, lines 14.01, 14.02, 25.50, and 25.51. Home office/related organization contract labor costs in the 2014-based IPPS market basket were calculated using a similar method except we used data reported on Worksheet S–3, Part II, column 4, line 14. As described previously, effective for cost reporting periods beginning on or after October 1, 2015 (Transmittal 10), Worksheet S–3, Part II was revised to add lines 14.01, 14.02, 25.50, 25.51, 25.52, and 25.53, to enhance the wage index data collection. Therefore, for the 2018-based IPPS market basket, we proposed to use these more detailed lines; however, the expenses captured on these lines would

be similar to the expenses originally reported on line 14, prior to the break out of the expenses on these new more detailed lines.

In addition, for the 2014-based IPPS market basket, we then multiplied the home office/related organization contract labor costs by the ratio of total Medicare-allowable operating costs to total operating costs. However, for the 2018-based IPPS market basket, we proposed to no longer apply this adjustment since the Medicare cost report instructions effective for Transmittal 10 now state that the costs reported on these lines should reflect costs associated with Medicare-allowable cost centers. Therefore, we no longer believe this adjustment is necessary.

b. Final Major Cost Category Computation

After we derived costs for the seven major cost categories for each provider using the Medicare cost report data as previously described, we proposed to address data outliers using the following steps. First, we divide the costs for each of the seven categories (calculated as previously described in this section) by total Medicare-allowable operating costs for the provider (calculated as previously described in this section) to obtain cost weights for each PPS hospital.

For each of the major cost weights except the Home Office/Related Organization Contract Labor cost weight, we proposed to trim the data to remove outliers (a standard statistical process) by: (1) Requiring that major expenses (such as Wages and Salaries costs) and total Medicare-allowable operating costs be greater than zero; and (2) excluding the top and bottom five percent of the major cost weight (for example, Wages and Salaries costs as a percent of total Medicare-allowable operating costs). We note that missing values are assumed to be zero consistent with the methodology for how missing values were treated in the 2014-based IPPS market basket. After the outliers have been removed, we sum the costs for each category across all remaining providers. We then divide this by the sum of total Medicare-allowable operating costs across all remaining providers to obtain a cost weight for the 2018-based IPPS market basket for the given category.

For the Home Office/Related Organization Contract Labor cost weight, we proposed to apply a trim that excludes those reporters above the 99th percentile. This allows all providers' Medicare-allowable costs to be included, even if their home office/related organization contract labor costs were reported to be zero. The Medicare cost report data (Worksheet S–2, Part I, line 140) indicate that not all hospitals have a home office. IPPS hospitals without a home office would report administrative costs that might typically be associated with a home office in the Wages and Salaries and Employee Benefits cost weights, or in the residual ''All Other'' cost weight if they purchased these types of services from external contractors. We believe the trimming methodology that excludes those who report a Home Office/Related Organization Contract Labor cost weight above the 99th percentile is appropriate as it removes extreme outliers while also allowing providers with zero home office/related organization contract labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation. Next, similar to the other cost weights, after the outliers have been removed, we sum the costs across all remaining providers. We then divide this by the sum of total Medicare-allowable operating costs across all remaining providers to obtain a cost weight for the 2018-based IPPS market basket.

The trimming process is done individually for each cost category so that providers excluded from one cost weight calculation are not automatically excluded from another cost weight calculation. We note that these proposed trimming methods are the same types of edits performed for the 2014-based IPPS market basket, as well as other PPS market baskets (including but not limited to SNF market basket and HHA market basket). We believe this trimming process improves the accuracy of the data used to compute the major cost weights by removing possible misreported data. We note that for each of the cost weights we evaluated the distribution of providers and costs by ownership-type, and by urban/rural status. For all of the cost weights, the trimmed sample was nationally representative.

Finally, we calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the seven cost categories listed. Table IV–01 shows the major cost categories and their respective cost weights as derived from the Medicare cost reports.

TABLE IV-01.—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major Cost Categories	2014-based IPPS Market Basket	Proposed 2018-based IPPS Market Basket
Wages and Salaries	42.1	39.7
Employee Benefits	12.0	11.3
Contract Labor	1.8	2.0
Professional Liability Insurance (Malpractice)	1.2	1.0
Pharmaceuticals	5.9	7.1
Blood and Blood Products	0.8	0.6
Home Office/Related Organization Contract Labor	4.2	5.9
"All Other" Residual	32.0	32.4

From 2014 to 2018, the Wages and Salaries and Employee Benefits cost weights as calculated directly from the Medicare cost reports decreased by approximately 2.4 percentage points and 0.7 percentage point, respectively, while the Contract Labor cost weight increased slightly by 0.2 percentage point.

As we did for the 2014-based IPPS market basket (82 FR 38162), we proposed to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions for employed labor under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2018 Medicare cost report data, this percentage is 78 percent. Therefore, we proposed to allocate approximately 78 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 22 percent to the Employee Benefits cost weight. The 2014-based IPPS market basket also allocated 78 percent of the Contract Labor cost weight to the Wages and Salaries cost weight.

Table IV–02 shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the 2014-based IPPS market basket and the proposed 2018-based IPPS market basket. In aggregate, the Compensation cost weight (calculated using more detailed decimal places) decreased from 55.8 percent to 53.0 percent, or 2.8 percentage points.

TABLE IV-02.—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major Cost Categories	2014-Based IPPS Market Basket	Proposed 2018-Based IPPS Market Basket
Total Compensation	**55.8**	**53.0**
Wages and Salaries	43.4	41.2
Employee Benefits	12.4	11.7

*Totals may not sum due to rounding

We received one comment on our proposed methodology for developing the major cost weights in the 2018-based IPPS market basket.

Comment: A commenter supported CMS' proposal to derive costs for blood and blood products for the 2018-based IPPS market basket from the CMS Medicare cost reports. However, they also encouraged CMS to develop and release additional educational materials that instruct hospitals on how to appropriately report blood products and services on the CMS Medicare cost reports. They further stated that blood products and services are captured in a wide variety of MS–DRGs, and providers may inadvertently exclude them from their cost reports. They stated they were committed to working with CMS to educate hospitals on appropriate billing for blood products.

Response: We appreciate the commenter's support of deriving blood and blood product costs using the Medicare cost report data. As previously stated, the blood and blood products cost weight is based on data reported in the Whole Blood & Packed Red Blood Cells cost center (line 62) and Blood Storing, Processing & Transfusion cost center (line 63) of the hospital Medicare cost reports. The instructions state these costs should include the direct expenses incurred: In obtaining blood directly from donors, in obtaining whole blood and packed red blood cells from suppliers and for processing, storing, and transfusing whole blood, packed red blood cells, and blood derivatives. We encourage hospitals to report these expenses consistent with the Medicare cost report instructions. We also welcome any specific suggestions that stakeholders may have on these instructions.

After consideration of the public comments we received, we are finalizing the methodology for deriving the major cost weights of the 2018-based IPPS market basket as proposed.

c. Derivation of the Detailed Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2018 Medicare cost report data into more detailed cost categories, we proposed to use the 2012 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 622000, Hospitals, published by the BEA. These data are publicly available at the following website: *http://www.bea.gov/industry/io_annual.htm.* The BEA Benchmark I–O data are generally scheduled for publication every 5 years on a lagged basis, with the most recent data available for 2012. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[759] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we proposed to inflate the detailed 2012 Benchmark I–O data forward to 2018 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. In our calculations for the proposed rule, we repeated this practice for each year. We then calculated the cost shares that each cost category represents of the 2012 data inflated to 2018. These resulting 2018 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2018-based IPPS market basket. For example, the cost for Food: Direct Purchases represents 4.8 percent of the sum of the ''All Other'' 2012 Benchmark I–O Hospital Expenditures inflated to 2018. Therefore, the Food: Direct Purchases cost weight represents 4.8 percent of the proposed 2018-based IPPS market basket's ''All Other'' cost category (32.4 percent), yielding a Food: Direct Purchases proposed cost weight of 1.6 percent in the proposed 2018-based IPPS market basket (0.048 × 32.4 percent = 1.6 percent). For the 2014-based IPPS market basket (82 FR 38162), we used the same methodology utilizing the 2007 Benchmark I–O data (aged to 2014).

Using this methodology, we proposed to derive 17 detailed cost categories

[759] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

from the proposed 2018-based IPPS market basket residual cost weight (32.4 percent). These categories are: (1) Fuel: Oil and Gas; (2) Electricity and Other Non-Fuel Utilities; (3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments; (7) Rubber and Plastics; (8) Paper and Printing Products; (9) Miscellaneous Products; (10) Professional Fees: Labor-Related; (11) Administrative and Facilities Support Services; (12) Installation, Maintenance, and Repair Services; (13) All Other: Labor-Related Services; (14) Professional Fees: Nonlabor-Related; (15) Financial Services; (16) Telephone Services; and (17) All Other: Nonlabor-Related Services.

The 2014-based IPPS market basket had a separate cost category for Water and Sewerage. Due to the size of the estimated cost weight (approximately 0.1 percent), we proposed that these costs be included in the Electricity and Other Non-Fuel Utilities cost category.

We received no comments on our proposed methodology for deriving the detailed cost weights of the 2018-based IPPS market basket and therefore are finalizing this methodology as proposed without modification.

2. Selection of Proposed Price Proxies

After computing the proposed 2018 cost weights for the IPPS market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for professional liability insurance (PLI), all the proxies we proposed are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- Producer Price Indexes—Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- Consumer Price Indexes—Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.
- Employment Cost Indexes—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- Reliability. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market basket levels are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.
- Availability. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

In this final rule, we present a detailed explanation of the price proxies that we proposed for each cost category weight. We note that many of the proxies that we proposed to use for the proposed 2018-based IPPS market basket are the same as those used for the 2014-based IPPS market basket.

(1) Wages and Salaries

We proposed to use the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code CIU1026220000000I) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(2) Employee Benefits

We proposed to use the ECI for Total Benefits for All Civilian Workers in Hospitals to measure the price growth of this cost category. This ECI is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code CIU10162200000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2014-based IPPS market basket.

(3) Fuel: Oil and Gas

Similar to the 2014-based IPPS market basket, we proposed to use a blend of the PPI Industry for Petroleum Refineries and the PPI Commodity for Natural Gas. Our analysis of the Bureau of Economic Analysis' 2012 Benchmark I–O data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that approximately 96 percent of hospital Fuel: Oil, and Gas expenses are for Petroleum Refineries (NAICS 324110) and Natural Gas (NAICS 221200) expenses, with Petroleum Refineries expenses accounting for approximately 90 percent and Natural Gas expenses accounting for approximately 10 percent of this sum. We proposed to create blended index of these expenses based on each NAICS' expenses as share of their sum. Therefore, we proposed to use a blend of 90 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU324110324110) and 10 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. The 2014-based IPPS market basket used a 70/30 blend of these price proxies, reflecting the 2007 I–O data (82 FR 38163). We believe that these two price proxies continue to be the most technically appropriate indices available to measure the price growth of the Fuel: Oil, and Gas cost category in the proposed 2018-based IPPS market basket.

(4) Electricity and Other Non-Fuel Utilities

We proposed to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category, as Electricity costs account for 93 percent of these expenses. This is the same price proxy used for the Electricity cost category in the 2014-based IPPS market basket. As previously noted, we proposed to include Water and Sewerage costs within the Electricity and Other Non-Fuel Utilities cost category, and to no longer use the CPI for Water and Sewerage Maintenance as we did for the 2014-based IPPS market basket, due to the small size of this estimated cost weight (approximately 0.1 percent).

(5) Professional Liability Insurance

We proposed to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collect commercial insurance medical liability premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This is the same price proxy used in the 2014-based IPPS market basket.

(6) Pharmaceuticals

We proposed to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(7) Food: Direct Purchases

We proposed to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(8) Food: Contract Services

We proposed to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(9) Chemicals

Similar to the 2014-based IPPS market basket, we proposed to use a four-part blended PPI as the proxy for the chemicals cost category in the proposed 2018-based IPPS market basket. The proposed blend is composed of the PPI Industry for Industrial Gas Manufacturing, Primary Products (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI Industry for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998). We note that the four part blended PPI used in the 2014-based IPPS market basket is composed of the PPI Industry for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI Industry for Soap and Cleaning Compound Manufacturing (BLS series code PCU32561–32561–). For the 2018-based IPPS market basket, we proposed to derive the weights for the PPIs using the 2012 Benchmark I–O data. The 2014-based IPPS market basket used the 2007 Benchmark I–O data to derive the weights for the four PPIs (82 FR 38164). We note that in the 2012 I–O data, the share of total chemicals expenses that the Soap and Cleaning Compound Manufacturing (NAICS 325610) represents decreased relative to the 2007 I–O data (from 5 percent to 2 percent), while the share of the total chemicals expenses that the All Other Chemical Product and Preparation manufacturing (NAICS 3259A0) categories represents increased (from 5 percent to 7 percent). As a result, we proposed to remove the PPI Industry for Soap and Cleaning Compound Manufacturing from the proposed blend for the proposed 2018-based IPPS market basket and replace it with the PPI Industry for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998).

Table IV–03 shows the proposed weights for each of the four PPIs used to create the blended index compared to those used for the 2014-based IPPS market basket.

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TABLE IV-03.—BLENDED CHEMICAL PPI WEIGHTS

NAICS	Name	2014-Based IPPS Weights	Proposed 2018-Based IPPS Weights
325120	PPI Industry for Industrial Gas Manufacturing	32%	19%
325180	PPI Industry for Other Basic Inorganic Chemical Manufacturing	17%	13%
325190	PPI Industry for Other Basic Organic Chemical Manufacturing	45%	60%
325610	PPI Industry for Soap and Cleaning Compound Manufacturing	6%	n/a
325998	PPI Industry for Other Miscellaneous Chemical Product Manufacturing	n/a	8%

(10) Blood and Blood Products

We proposed to use the PPI Industry for Blood and Organ Banks (BLS series code PCU621991621991) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(11) Medical Instruments

We proposed to use a blended price proxy for the Medical Instruments category, as shown in Table IV–04. The 2012 Benchmark I–O data shows the majority of medical instruments and supply costs are for NAICS 339112—Surgical and medical instrument manufacturing costs (approximately 56 percent) and NAICS 339113—Surgical appliance and supplies manufacturing costs (approximately 43 percent). Therefore, we proposed to use a blend of these two price proxies. To proxy the price changes associated with NAICS 339112, we proposed using the PPI—Commodity—Surgical and medical instruments (BLS series code

WPU1562). This is the same price proxy we used in the 2014-based IPPS market basket. To proxy the price changes associated with NAICS 339113, we proposed to use a 50/50 blend of the PPI—Commodity—Medical and surgical appliances and supplies (BLS series code WPU1563) and the PPI—Commodity—Miscellaneous products—Personal safety equipment and clothing (BLS series code WPU1571). We proposed to include the latter price proxy as it would reflect personal protective equipment including but not limited to face shields and protective clothing. The 2012 Benchmark I–O data does not provide specific expenses for these products; however, we recognize that this category reflects costs faced by IPPS hospitals.

TABLE IV-04.—BLENDED MEDICAL INSTRUMENTS PPI WEIGHTS

NAICS	Name	2014-Based IPPS Weights	Proposed 2018-Based IPPS Weights
339112	PPI - Commodity - Surgical and medical instruments	50%	56%
339113	PPI - Commodity - Medical and surgical appliances and supplies	50%	22%
	PPI - Commodity - Miscellaneous products-Personal safety equipment and clothing	n/a	22%

(12) Rubber and Plastics

We proposed to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(13) Paper and Printing Products

We proposed to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(14) Miscellaneous Products

We proposed to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(15) Professional Fees: Labor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This is the same price proxy used in the 2014-based IPPS market basket.

(16) Administrative and Facilities Support Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same price proxy used in the 2014-based IPPS market basket.

(17) Installation, Maintenance, and Repair Services

We proposed to use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same proxy used in the 2014-based IPPS market basket.

(18) All Other: Labor-Related Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(19) Professional Fees: Nonlabor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same price proxy that we proposed to use for the Professional Fees: Labor-Related cost category and the same price proxy used in the 2014-based IPPS market basket.

(20) Financial Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(21) Telephone Services

We proposed to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(22) All Other: Nonlabor-Related Services

We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket. This is the same price proxy used in the 2014-based IPPS market basket.

We received no comments on the proposed price proxies in the 2018-based IPPS market basket and therefore are finalizing this proposal without modification.

Table IV–05 sets forth the 2018-based IPPS market basket, including the cost categories and their respective weights and price proxies. For comparison purposes, the corresponding 2014-based IPPS market basket cost weights also are listed.

TABLE IV-05.— 2018-BASED IPPS MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO 2014-BASED IPPS MARKET BASKET COST WEIGHTS

Cost Categories	2014-Based IPPS Market Basket Cost Weights	2018-Based IPPS Market Basket Cost Weights	2018-Based IPPS Market Basket Price Proxies
1. Compensation	55.8	53.0	--
A. Wages and Salaries[1]	43.4	41.2	ECI for Wages and Salaries for All Civilian Workers in Hospitals
B. Employee Benefits[1]	12.4	11.7	ECI for Total Benefits for All Civilian Workers in Hospitals
2. Utilities	2.5	2.3	--
A. Electricity and Other Non-Fuel Utilities[2]	1.1	1.5	PPI Commodity for Commercial Electric Power
B. Fuel: Oil and Gas	1.3	0.8	Blend of PPIs for Petroleum Refineries and Natural Gas
3. Professional Liability Insurance	1.2	1.0	CMS Hospital Professional Liability Insurance Premium Index
4. All Other	40.5	43.8	--
A. All Other Products	17.4	18.4	--

Cost Categories	2014-Based IPPS Market Basket Cost Weights	2018-Based IPPS Market Basket Cost Weights	2018-Based IPPS Market Basket Price Proxies
(1.) Pharmaceuticals	5.9	7.1	PPI Commodity for Pharmaceuticals for Human Use, Prescription
(2.) Food: Direct Purchases	2.3	1.6	PPI Commodity for Processed Foods and Feeds
(3.) Food: Contract Services	1.3	1.8	CPI for Food Away From Home (All Urban Consumers)
(4.) Chemicals	0.9	0.6	Blend of Chemical PPIs
(5.) Blood and Blood Products	0.8	0.6	PPI Industry for Blood and Organ Banks
(6.) Medical Instruments	2.9	4.1	Blend of PPIs
(7.) Rubber and Plastics	0.8	0.6	PPI Commodity for Rubber and Plastic Products
(8.) Paper and Printing Products	1.5	0.9	PPI Commodity for Converted Paper and Paperboard Products
(9.) Miscellaneous Products	1.1	1.2	PPI Commodity for Finished Goods less Food and Energy
B. Labor-Related Services	12.5	14.7	--
(1.) Professional Fees: Labor-Related	6.8	8.6	ECI for Total Compensation for Private Industry Workers in Professional and Related
(2.) Administrative and Facilities Support Services	1.0	1.1	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
(3.) Installation, Maintenance and Repair Services	2.4	2.4	ECI for Total Compensation for Civilian Workers in Installation, Maintenance, and Repair
(4.) All Other: Labor-Related Services	2.3	2.6	ECI for Total Compensation for Private Industry Workers in Service Occupations
C. Nonlabor-Related Services	10.7	10.7	--
(1.) Professional Fees: Nonlabor-Related	5.1	7.0	ECI for Total Compensation for Private Industry Workers in Professional and Related
(2.) Financial Services	3.0	1.4	ECI for Total Compensation for Private Industry Workers in Financial Activities
(3.) Telephone Services	0.8	0.4	CPI for Telephone Services
(4.) All Other: Nonlabor-Related Services	1.7	1.8	CPI for All Items less Food and Energy
Total	100.0	100.0	--

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

[2] We are including Water and Sewerage costs in the Electricity and Non-Fuel Utilities cost category in the 2018-based IPPS market basket. These costs were broken out separately in the 2014-based IPPS market basket.

Table IV–06 compares both the historical and forecasted percent changes in the 2014-based IPPS market basket and the 2018-based IPPS market basket. The forecasted growth rates in Table IV–06 are based on IHS Global

Inc.'s (IGI's) second quarter 2021 forecast with historical data through first quarter 2021.

TABLE IV-06.--2014-BASED AND 2018-BASED IPPS HOSPITAL OPERATING INDEX PERCENT CHANGE, FY 2017 THROUGH FY 2024

Fiscal Year (FY)	2014-Based IPPS Market Basket Percent Change	2018-Based IPPS Market Basket Percent Change
Historical data:		
FY 2017	2.6	2.5
FY 2018	2.5	2.5
FY 2019	2.4	2.4
FY 2020	2.0	2.0
Average FYs 2017-2020	**2.4**	**2.4**
Forecast:		
FY 2021	2.7	2.7
FY 2022	2.7	2.7
FY 2023	2.8	2.8
FY 2024	2.9	2.9
Average FYs 2021-2024	**2.8**	**2.8**

Source: IHS Global, Inc., 2nd Quarter 2021 forecast.

There is no difference between the average percent change in the 2014-based and the 2018-based IPPS market basket over the FY 2017 through FY 2020 time period. For FY 2022, the increase is projected to be 2.7 percent for both the 2014-based and 2018-based IPPS market baskets.

3. Labor-Related Share

Under section 1886(d)(3)(E) of the Act, the Secretary estimates from time to time the proportion of payments that are labor-related. Section 1886(d)(3)(E) of the Act states that the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.''

The labor-related share is used to determine the proportion of the national PPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are *labor intensive* and *vary with the local labor market.* For the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to include in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the proposed 2018-based IPPS market basket: Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, and All Other: Labor-Related Services, as we did in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38167).

Similar to the 2014-based IPPS market basket, we proposed that the Professional Fees: Labor-Related cost category includes expenses associated with advertising and a proportion of legal services, accounting and auditing, engineering, and management consulting. As was done in the 2014-based IPPS market basket rebasing, we proposed to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008 (OMB Control Number 0938–1036). We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and received no comments (71 FR 8588).

A discussion of the composition of the survey and poststratification can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We proposed to apply each of these percentages to its respective Benchmark I–O cost category underlying the professional fees cost category. This is the methodology that we used to separate the 2014-based IPPS market basket professional fees cost category into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories. We proposed to use the same methodology and survey results to separate the professional fees costs for the proposed 2018-based IPPS market basket into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories. We stated that we believe these survey results are appropriate to use for the proposed 2018-based IPPS market basket as they empirically determine the proportion of contracted professional services purchased by the industry that is attributable to local firms and the proportion that is purchased from national firms.

In the proposed 2018-based IPPS market basket, nonmedical professional

fees that were subject to allocation based on these survey results represent approximately 6.4 percent of total operating costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we proposed to apportion 4.1 percentage points of the 6.4 percentage point figure into the Professional Fees: Labor-Related share cost category and designate the remaining approximately 2.3 percentage points into the Professional Fees: Nonlabor-Related cost category.

In addition to the professional services listed earlier, we also classify a proportion of the Home Office/Related Organization cost weight into the Professional Fees: Labor-Related cost category as was done in the previous rebasing. We believe that many of these costs are labor-intensive and vary with the local labor market. However, data indicate that not all IPPS hospitals with home offices have home offices located in their local labor market. Therefore, we proposed to include in the labor-related share only a proportion of the Home Office/Related Organization cost weight based on the methodology described in this final rule.

For the proposed 2018-based IPPS market basket, based on Medicare cost report data, we found that approximately 65 percent of IPPS hospitals reported some type of home office information on their Medicare cost report for 2018 (for example, city, State, and zip code). Using the data reported on the Medicare cost report, we compared the location of the hospital with the location of the hospital's home office. We then determined the proportion of costs that should be allocated to the labor-related share based on the percent of total hospital home office/related organization contract labor costs for those hospitals that had home offices located in their respective local labor markets—defined as being in the same MSA. We determined a hospital's and home office's MSAs using their zip code information from the Medicare cost report.

Based on these data, we determined the proportion of costs that should be allocated to the labor-related share based on the percent of hospital home office/related organization contract labor costs (equal to the sum of Worksheet S–3, Part II, column 4, lines 14.01, 14.02, 25.50, and 25.51). Using this methodology, we determined that 60 percent of hospitals' home office compensation costs were for home offices located in their respective local labor markets. Therefore, we proposed to allocate 60 percent of Home Office/Related Organization cost weight to the labor-related share. This is the same proportion we used for the 2014-based IPPS market basket, which was based on 2014 Medicare cost report data.

In the proposed 2018-based IPPS market basket, the Home Office/Related Organization cost weight that is subject to allocation based on the home office allocation methodology represent 5.9 percent of total operating costs. Based on the results of the home office analysis, as previously discussed, we apportioned approximately 3.5 percentage points of the 5.9 percentage points figure into the Professional Fees: Labor-Related cost category and designated the remaining approximately 2.4 percentage points into the Professional Fees: Nonlabor-Related cost category. In summary, based on the two previously mentioned allocations, we apportioned 7.6 percentage points of the professional fees and home office cost weights into the Professional Fees: Labor-Related cost category. This amount is added to the portion of professional fees that we already identified as labor-related using the I–O data such as contracted advertising and marketing costs (approximately 1.0 percentage point of total operating costs) resulting in a Professional Fees: Labor-Related cost weight of 8.6 percent.

Table IV–07 presents a comparison of the proposed 2018-based labor-related share and the 2014-based labor-related share. As discussed in section IV.B.1.b. of the preamble of this final rule, the Wages and Salaries and Employee Benefits cost weights reflect contract labor costs.

TABLE IV-07.—COMPARISION OF THE 2014-BASED LABOR-RELATED SHARE AND THE PROPOSED 2018-BASED LABOR-RELATED SHARE

	2014-Based IPPS Market Basket Cost Weights	2018-Based IPPS Market Basket Cost Weights
Wages and Salaries	43.4	41.2
Employee Benefits	12.4	11.7
Professional Fees: Labor-Related	6.8	8.6
Administrative and Facilities Support Services	1.0	1.1
Installation, Maintenance, and Repair Services	2.4	2.4
All Other: Labor-Related Services	2.3	2.6
Total Labor-Related Share	**68.3**	**67.6**

Note: Detail may not add to total due to rounding.

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Using the cost category weights from the 2018-based IPPS market basket, we calculated a labor-related share of 67.6 percent, approximately 0.7 percentage point lower than the current labor-related share of 68.3 percent. This downward revision to the labor-related share is the net effect of two impacts. First, we updated the base year cost weights from 2014 to 2018 (−1.8 percentage points), which reflects a −2.8 percentage point revision from the compensation cost weight and a +1.0 percentage point revision from the labor-related portion of Home Office/Related Organization Contract Labor cost weight (60 percent of total cost weight). Second, there is an upward revision of 1.1 percentage points from the impact of updating the detailed cost

weights to reflect 2012 Input-Output data.

Therefore, we proposed to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021. We continue to believe, as we have stated in the past, that these operating cost categories are related to, influenced by, or vary with the local markets. Therefore, our definition of the labor-related share continues to be consistent with section 1886(d)(3) of the Act. We note that section 403 of Public Law 108–173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless 62 percent would result in lower payments to a hospital than would otherwise be made.

We received several comments regarding our calculation of the proposed labor-related share based on the 2018-based IPPS market basket.

Comment: Many commenters opposed the proposed change to the labor-related share from 68.3 percent to 67.6 percent. Several commenters stated that this is in large part because they disagree with some of the assumptions underlying this proposal. They stated that they are concerned that the methodology CMS uses to rebase and revise the labor-related share is premised on the flawed assumption that some categories of labor costs are not subject to geographic variation.

Several commenters disagreed with CMS' proposal to exclude from the labor-related share the proportion of non-medical professional services fees presumed to have been purchased outside of the hospital's labor market. The commenters disagreed with CMS' assertion/assumption that services purchased from national firms are not affected by the local labor market. In the commenters' experience, national firms adjust their rates for different reasons, including reasons that are largely dictated by local labor costs. The commenters stated that when hospitals seek professional services, the services they are seeking (for example accounting, engineering, management consulting) typically are not so unique that they could only be provided by regional or national firms. The commenters stated that CMS' own survey data support this conclusion, as approximately 60 percent of these services are sourced from firms in the local market. The commenters stated that costs of services purchased from firms outside the hospital's labor market should be included with the labor-related share of costs.

Response: We disagree with the commenters and believe it is appropriate that a proportion of Accounting & Auditing, Legal, Engineering, and Management Consulting services costs purchased by hospitals should be excluded from the labor-related share. Section 1886(d)(3)(E)(i) of the Act directs the Secretary to adjust the proportion of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. It also directs the Secretary to estimate from time to time this proportion of hospital costs that are labor-related.

The purpose of the labor-related share is to reflect the proportion of the national PPS base payment rate that is adjusted by the hospital's wage index (representing the relative costs of their local labor market to the national average). Therefore, we include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market.

As acknowledged by the commenter and confirmed by the survey of hospitals conducted by CMS in 2008 (as stated above), professional services can be purchased from local firms as well as national and regional professional services firms. It is not necessarily the case, as asserted by the commenter, that these national and regional firms have fees that match those in the local labor market even though providers have the option to utilize those firms. That is, fees for services purchased from firms outside the local labor market may differ from those that would be purchased in the local labor market for any number of reasons (including but not limited to, the skill level of the contracted personnel, higher capital costs, etc.). The approximately 64 percent of the Professional Fees cost weight allocated to the Professional Fees: Labor-related cost weight based on the survey results reflect the commenter's assertion that not all Professional Fees services are purchased in the local labor market. We believe it is reasonable to conclude that those services purchased directly within the local labor market are directly related to local labor market conditions and, thus, should be included in the labor-related share. The remaining 36 percent would reflect different and additional factors outside the local labor market and, thus, should be excluded from the labor related share.

The 64 percent is based on a survey conducted by CMS in 2008 as detailed in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). This was also used to determine the Professional Fees: Labor-related cost weight in the 2014-based IPPS market basket. We would note that CMS is in the process of proposing an additional question to the hospital Medicare cost reports (CMS Form 2552–2010; OMB Number 0938–0050) to help better determine which proportion of Accounting & Auditing, Legal, Engineering, and Management Consulting services costs are purchased from the local labor market (85 FR 71654). We encourage hospitals to fill out this question (if finalized) in future Medicare cost report submissions.

Therefore, for the reasons discussed, we believe our proposed methodology of allocating only a portion of Professional Fees to the Professional Fees: Labor-Related cost category is appropriate.

Comment: Several commenters disagreed with the assumption that home office compensation costs that occur outside of a hospital's labor market are not subject to geographic wage variation, and stated that they do not believe that the proposed reclassification to the Professional Fees: Non-Labor-Related cost category is justified. The commenters stated that the proposed methodology fails to consider that the home office is essentially a part of the hospital, and thus the hospital, along with its home office, is operating in multiple labor markets. The commenters stated that the home office's portion of the hospital's labor costs should not be excluded from the labor-related share simply because they are not in the same labor market as the hospital.

The commenters stated that even if the wage-index adjustment applied to hospital payments is not sufficiently refined to recognize this multi-labor-market circumstance, that is no reason to completely eliminate the recognition of these costs under the IPPS as being affected by local labor market forces. The commenters stated that the proposed methodology seems particularly unfair to independent hospitals in high-wage areas with no home office costs that will see their reimbursement lowered through a reduction in the labor-related share because a portion of other hospitals' administrative costs have been removed. Therefore, the commenters requested that CMS treat 100 percent of home office labor costs as being ''labor related.''

A commenter conducted their own analysis of the FY 2018 Medicare cost report data showing that providers with

a home office outside of their local labor market were located in areas with a wage index below 1 as well as greater than 1. The commenter stated that those hospitals in a labor market with a wage index greater than 1 had a mean home office average hourly wage costs that were greater than the mean home office average hourly wage costs of those hospitals in a labor market with a wage index less than 1. The commenter claimed that these data indicate that, contrary to CMS' assertion, home office salary, wage, and benefit costs for hospitals with home offices outside of their labor market are subject to geographic wage variation.

The commenter stated that the agency is not adjusting the full proportion of hospitals' wages and wage-related costs subject to geographic variation by excluding a cumulative 4.7 percentage points of the Non-Medical Professional Fees (2.3 percentage points) and Home Office/Related Organization (2.4 percentage points) cost weights from the labor-related share.

Response: As previously stated, the purpose of the labor-related share is to determine the proportion of the national PPS base payment rate that is adjusted by the hospital's wage index (representing the relative costs of their local labor market to the national average). Therefore, we include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market.

As the commenter stated and as validated with the Medicare cost report, a hospital's home office can be located outside the hospital's local labor market. The proposed methodology for allocating 60 percent of the Home Office/Related Organization cost weight (reflecting compensation costs) is consistent with the intent of the statute to identify the proportion of costs likely to directly vary with the hospital's local labor market. Our methodology relies on the Medicare cost report data for hospitals reporting home office information to determine whether their home office is located in the same local labor market (which we define as the hospital's Metropolitan Statistical Area). Similar to our rationale as previously discussed, for professional fees, we believe it is reasonable to conclude that those home office services purchased directly within the local labor market are directly related to local labor market conditions while the remaining 40 percent would reflect different and additional factors and, thus, should be excluded from the labor related share.

Therefore, we believe our proposed methodology of only allocating a portion of the Home Office/Related Organization cost weight into the Professional Fees: Labor-related cost weight is appropriate.

Comment: A commenter stated that as with the adoption of OMB Bulletin 18–04, which revises the core-based statistical areas (CBSAs) that drive the Medicare wage index, CMS is relying upon 2018 data for its proposal to reduce the labor-related component. The commenter stated that they believe this 2018 data has been made stale by the onset of the current COVID–19 pandemic, which caused significant shifts in the labor markets, particularly with regard to wages and fringe benefits.

The commenter stated that the reduction in the labor-related share has a disproportionate and significant impact on hospitals in the greater New York metropolitan area. The commenter estimated that the impact of this proposal for Suburban Hospital Alliance members is another $9.6 million in reduced reimbursements. The commenter stated that for these reasons, they urge CMS to postpone adjustments to the labor component until 2020 Census data can be fully analyzed and incorporated into the rates.

A commenter noted that CMS last rebased the hospital market basket cost weights effective for FY 2018, with 2014 data for the base period. For FY 2022, CMS proposes to rebase the IPPS operating market basket to reflect the 2018 cost structure for IPPS hospitals. The commenter is concerned that the data may not be as generalizable to FY 2022 like previous years given the effects of COVID–19 on both hospitals and other providers directly and to the economy more broadly. They agree with CMS that it should continue to monitor the upcoming Medicare cost report data to see if a more frequent rebasing schedule is necessary. To the extent CMS is already aware of, or is made aware of, cost increases due to COVID–19 (for example, staffing, creating new/alternative care sites), they recommend the agency consider temporary modifications to better account for such changes in determining the market basket.

A few commenters stated that although Federal law requires the Secretary to update market basket weights, including the labor share, more frequently than every five years, it does not dictate the methodology for doing so. The commenters stated that the COVID–19 emergency has had an unusual and unexpected impact on hospital wages in many places, and especially in urban areas with already higher-than-average wages (that is, wage indexes greater than 1.0). The commenters stated that the proposed reduction of the labor-related share would apply only to geographic areas with a wage index greater than 1.0 and would therefore reduce reimbursement to those very hospitals that already faced the highest labor costs just as those costs are further increasing in response to the public health emergency. The commenters stated that it is too soon to measure that impact and impose this type of cut on so many hospitals.

Response: We appreciate the commenters' concerns regarding how operating expenses for hospitals may have been impacted by the PHE. However, we disagree with the commenters that the update of the labor-related share should be postponed. As published in the FY 2006 IPPS final rule (70 FR 47403), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket, including the labor-related share, of every four years. Therefore, our proposal is consistent with this finalized policy to update the labor-related share to reflect the rebased and revised IPPS market basket, which is now based on 2018 data. Additionally, it is a technical improvement for the labor related share to reflect more current data (2018) than maintain a share based on older (2014) data.

The market basket cost share weights are based on the relative shares of expenses by category. In order to evaluate the impact of the PHE on the market basket cost weights, CMS would need to have a complete dataset that would provide expenditure levels for all categories of expenses to determine the relative shares of each cost category. However, there is not a comprehensive set of 2020 cost data for hospitals available at this time. As stated previously, we plan to review the Medicare cost report data as soon as complete information is available and evaluate these data for future rulemaking.

After consideration of the public comments we received, we are finalizing the 2018-based IPPS market basket and labor-related share as proposed.

C. Market Basket for Certain Hospitals Presently Excluded From the IPPS

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857), we adopted the use of the FY 2006-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals and religious nonmedical health care institutions (RNHCIs). Children's hospitals and PPS-

excluded cancer hospitals and RNHCIs are still reimbursed solely under the reasonable cost-based system, subject to the rate-of-increase limits. Under these limits, an annual target amount (expressed in terms of the inpatient operating cost per discharge) is set for each hospital based on the hospital's own historical cost experience trended forward by the applicable rate-of-increase percentages.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50603), under the broad authority in sections 1886(b)(3)(A) and (B), 1886(b)(3)(E), and 1871 of the Act and section 4454 of the BBA, consistent with our use of the IPPS operating market basket percentage increase to update target amounts, we adopted the use of the FY 2010-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, and RNHCIs that are paid on the basis of reasonable cost subject to the rate-of-increase limits under § 413.40. In addition, as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also used the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for short–term acute care hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). These hospitals also are paid on the basis of reasonable cost, subject to the rate-of-increase limits under § 413.40. In the FY 2018 IPPS/LTCH PPS final rule, we finalized the use of the 2014-based IPPS operating market basket for FY 2018 and subsequent fiscal years to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located outside the 50 states, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are paid on the basis of reasonable cost subject to the rate-of-increase limits under § 413.40. We refer the reader to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38170) for discussion of why we believe it is appropriate to use the percentage increase in the IPPS operating market basket to update the target amounts for these excluded facilities.

As discussed in this section IV. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to rebase and revise the IPPS operating market basket to a 2018 base year. We continue to believe that it is appropriate to use the increase in the IPPS operating market basket to update the target amounts for these excluded facilities, as discussed in prior rulemaking. Therefore, we proposed to use the percentage increase in the proposed 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located outside the 50 states, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) for FY 2022 and subsequent fiscal years. Accordingly, for FY 2022, the rate-of increase percentage to be applied to the target amount for these hospitals would be the FY 2022 percentage increase in the 2018-based IPPS operating market basket.

We received no comments on this proposal and therefore are finalizing this proposal without modification.

D. Rebasing and Revising the Capital Input Price Index (CIPI)

The CIPI was originally described in the FY 1993 IPPS final rule (57 FR 40016). There have been subsequent discussions of the CIPI presented in the IPPS proposed and final rules. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38170 through 38175) described the most recent rebasing and revising of the CIPI to a 2014 base year, which reflected the capital cost structure of IPPS hospitals available at that time.

For the FY 2022 IPPS update, we proposed to rebase and revise the CIPI to a 2018 base year to reflect a more current structure of capital costs for IPPS hospitals. This proposed 2018-based CIPI was derived using 2018 cost reports for IPPS hospitals, which includes providers whose cost reporting period began on or after October 1, 2017, and prior to September 30, 2018. We also proposed to start with the same subset of Medicare cost reports from IPPS hospitals as previously described in section IV.B.1.a. of the preamble of this rule. As with the 2014-based index, we proposed to develop two sets of weights to derive the proposed 2018-based CIPI. The first set of weights identifies the proportion of hospital capital expenditures attributable to each expenditure category, while the second set of weights is a set of relative vintage weights for depreciation and interest. The set of vintage weights is used to identify the proportion of capital expenditures within a cost category that is attributable to each year over the useful life of the capital assets in that category. A more thorough discussion of vintage weights is provided later in this section.

Using 2018 Medicare cost reports, we are able to obtain capital costs for the following categories: Depreciation, Interest, Lease, and Other. Specifically, we proposed to determine what proportion of total capital costs that each category represents using the data reported by IPPS hospitals on Worksheet A–7, Part III. As shown in the left column of Table IV–08, in 2018 depreciation expenses accounted for 67.5 percent of total capital costs, interest expenses accounted for 14.6 percent, leasing expenses accounted for 13.3 percent, and other capital expenses accounted for 4.7 percent.

We also proposed to allocate lease costs across each of the remaining capital cost categories as was done in the 2014-based CIPI. We proposed to proportionally distribute leasing costs among the cost categories of Depreciation, Interest, and Other, reflecting the assumption that the underlying cost structure of leases is similar to that of capital costs in general. As was done for the 2014-based CIPI, we proposed to assume that 10 percent of the lease costs as a proportion of total capital costs represents overhead and to assign those costs to the Other capital cost category accordingly. Therefore, we assumed that approximately 1.3 percent (13.3 percent $\times$ 0.1) of total capital costs represent lease costs attributable to overhead, and we proposed to add this 1.3 percent to the 4.7 percent Other cost category weight. We then proposed to distribute the remaining lease costs (12.0 percent, or 13.3 percent $-$ 1.3 percent) proportionally across the three cost categories (Depreciation, Interest, and Other) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other cost categories (excluding lease expenses). For example, the Other cost category represented 5.4 percent of all three cost categories (Depreciation, Interest, and Other) prior to any lease expenses being allocated. This 5.4 percent is applied to the 12.0 percent of remaining lease expenses so that another 0.6 percent of lease expenses as a percent of total capital costs is allocated to the Other cost category. Therefore, the resulting proposed Other cost weight is 6.6 percent (4.7 percent + 1.3 percent + 0.6 percent). This is the same methodology used for the 2014-based CIPI. The resulting cost weights of the proposed allocation of lease expenses are shown in the right column of Table IV–08.

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TABLE IV-08.—PROPOSED ALLOCATION OF LEASE EXPENSES FOR THE PROPOSED 2018-BASED CIPI

Cost Categories	Proposed Cost Shares Obtained from Medicare Cost Reports (Percent of Total Capital Costs)	Proposed Cost Shares After Allocation of Lease Expenses (Percent of Total Capital Costs)
Depreciation	67.5	76.8
Interest	14.6	16.6
Lease	13.3	-
Other	4.7	6.6

Note: Detail may not add to 100 percent due to rounding

Finally, we proposed to further divide the Depreciation and Interest cost categories. We proposed to separate the Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also proposed to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For-profit.

To disaggregate the depreciation cost weight, we needed to determine the percent of total depreciation costs for IPPS hospitals (after the allocation of lease costs) that are attributable to building and fixed equipment, which we hereafter refer to as the ''fixed percentage.'' Based on Worksheet A–7, Part III data from the 2018 IPPS Medicare cost reports, we have determined that depreciation costs for building and fixed equipment account for approximately 51 percent of total depreciation costs, while depreciation costs for movable equipment account for approximately 49 percent of total depreciation costs. As was done for the 2014-based CIPI, we proposed to apply this fixed percentage to the depreciation cost weight (after leasing costs are included) to derive a Depreciation cost weight attributable to Building and Fixed Equipment and a Depreciation cost weight attributable to Movable Equipment.

To disaggregate the interest cost weight, we needed to determine the percent of total interest costs for IPPS hospitals that are attributable to government and nonprofit facilities, which we hereafter refer to as the ''nonprofit percentage,'' because interest price pressures tend to differ between nonprofit and for-profit facilities. We proposed to use interest costs data from Worksheet A–7, Part III of the 2018 Medicare cost reports for IPPS hospitals, which is the same methodology used for the 2014-based CIPI. The nonprofit percentage determined using this method is 90 percent. Table IV–09 in the proposed rule provided a comparison of the 2014-based CIPI cost weights and the proposed 2018-based CIPI cost weights. This table is also included below and reflects the final 2018-based CIPI cost weights.

We received no comments on the methodology to derive the cost weights of the proposed 2018-based CIPI and therefore are finalizing this methodology without modification.

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. With the exception of the For-profit interest cost category, we proposed to apply the same price proxies as were used in the 2014-based CIPI, which are listed in Table IV–09. We also proposed to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same method that was used for the 2014-based CIPI and is described later in this section of this rule.

We proposed to continue to proxy the Depreciation—Building and Fixed Equipment cost category by the BEA Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type). As stated in the FY 2010 IPPS/LTCH final rule (74 FR 43860), for the FY 2006-based CIPI we finalized the use of this index to measure the price growth of this cost category. This BEA index is intended to capture prices for construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. For the Depreciation—Movable Equipment cost category, we proposed to continue to measure the price growth using the PPI Commodity for Machinery and Equipment (BLS series code WPU11). This price index reflects price inflation associated with a variety of machinery and equipment that would be utilized by hospitals including but not limited to communication equipment, computers, and medical equipment. For the Nonprofit Interest cost category, we proposed to continue to measure the price growth using the average yield on domestic municipal bonds (Bond Buyer 20-bond index).

For the For-profit Interest cost category, we proposed to use the iBoxx AAA Corporate Bond Yield index instead of the Moody's AAA Corporate Bond Yield index that was used for the 2014-based IPPS market basket. Effective for December 2020, the Moody's AAA Corporate Bond series is no longer available for use under license to IGI, the nationally-recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and MFP. Therefore, we proposed to replace the price proxy for the For-profit Interest cost category. We compared the iBoxx AAA Corporate Bond Yield index with the Moody's AAA Corporate Bond Yield index and found that the average growth rates in the two series were similar. Over the historical time period of FY 2000 to FY 2020, the 4-quarter percent change moving average growth in the iBoxx series was approximately 0.1 percentage point higher, on average, than the Moody's AAA corporate Bond Yield index.

For the Other capital cost category (including insurances, taxes, and other capital-related costs), we proposed to continue to measure the price growth using the CPI for Rent of Primary Residence (All Urban Consumers) (BLS series code CUUS0000SEHA), which would reflect the price growth of these costs. We believe that these price proxies continue to be the most appropriate proxies for IPPS capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

We received no comments on our proposed price proxies for the 2018-

based CIPI and therefore are finalizing without modification.

TABLE IV-09.— 2018-BASED CIPI COST WEIGHTS AND PRICE PROXIES COMPARED TO 2014-BASED CIPI COST WEIGHTS

Cost Categories	2014 Cost Weights	2018 Cost Weights	Price Proxy
Total	100.0	100.0	
Depreciation	74.4	76.8	
Building and Fixed Equipment	36.7	39.3	BEA's Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care
Movable Equipment	37.7	37.5	PPI Commodity for Machinery and Equipment
Interest	18.2	16.6	
Government/Nonprofit	15.7	14.9	Average Yield on Domestic Municipal Bonds (Bond Buyer 20-Bond Index)
For-Profit	2.5	1.7	Average Yield on iBoxx AAA Corporate Bonds
Other	7.4	6.6	CPI for Rent of Primary Residence

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted 2018-based CIPI is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest.

Vintage weights are an integral part of the CIPI. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for IPPS capital costs. The CIPI reflects the underlying stability of the capital acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we first needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital purchases by hospitals for all of the previously noted components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. Data we obtained from the American Hospital Association (AHA) did not include annual capital purchases. However, we were able to obtain data on total expenses back to 1963 from the AHA. Consequently, we proposed to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then proposed to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2018. We proposed to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derived annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. We used the AHA data and similar methodology to derive the 2014-based IPPS capital market basket.

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for building and fixed equipment, movable equipment, and interest for the proposed 2018-based CIPI. We proposed to calculate the expected lives using Medicare cost report data. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 27 years, and the average expected life of movable equipment to be equal to 12 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that the 2014-based CIPI was also based on an expected average life of building and fixed equipment of 27 years and an expected average life of movable equipment of 12 years.

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage

weights, we proposed to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as provided earlier in this final rule. For the interest vintage weights, we proposed to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital purchases time series specific to each asset type, we proposed to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 27 years, and in the case of movable equipment, 12 years). For each asset type, we proposed to use the time series of annual capital purchases amounts available from 2018 back to 1964. These data allow us to derive twenty-nine 27-year periods of capital purchases for building and fixed equipment and interest, and forty-four 12-year periods of capital purchases for movable equipment. For each 27-year period for building and fixed equipment and interest, or 12-year period for movable equipment, we proposed to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 27-year or 12-year period. This calculation was done for each year in the 27-year or 12-year period and for each of the periods for which we have data. We then calculated the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

We received no comments on our proposed vintage weights and therefore are finalizing without modification.

The vintage weights for the 2018-based CIPI and the 2014-based CIPI are presented in Table IV–10.

TABLE IV-10.-- 2018-BASED CIPI AND 2014-BASED CIPI VINTAGE WEIGHTS

	Building and Fixed Equipment		Movable Equipment		Interest	
Year[1]	2018-Based 27 years	2014-Based 27 years	2018-Based 12 years	2014-Based 12 years	2018-Based 27 years	2014-Based 27 years
1	0.026	0.024	0.064	0.062	0.015	0.012
2	0.028	0.025	0.069	0.064	0.016	0.014
3	0.029	0.027	0.072	0.070	0.018	0.015
4	0.031	0.028	0.075	0.074	0.019	0.017
5	0.032	0.030	0.078	0.078	0.021	0.019
6	0.032	0.031	0.082	0.082	0.022	0.021
7	0.033	0.033	0.086	0.086	0.023	0.023
8	0.034	0.034	0.088	0.088	0.026	0.025
9	0.036	0.035	0.091	0.092	0.028	0.027
10	0.036	0.036	0.095	0.097	0.029	0.029
11	0.036	0.037	0.099	0.102	0.029	0.030
12	0.036	0.039	0.101	0.105	0.031	0.033
13	0.037	0.040	-	-	0.033	0.035
14	0.038	0.040	-	-	0.036	0.037
15	0.039	0.039	-	-	0.039	0.037
16	0.040	0.039	-	-	0.041	0.040
17	0.041	0.040	-	-	0.044	0.041
18	0.042	0.042	-	-	0.046	0.045
19	0.041	0.042	-	-	0.047	0.048
20	0.041	0.042	-	-	0.049	0.050
21	0.042	0.043	-	-	0.052	0.052
22	0.042	0.043	-	-	0.053	0.054
23	0.042	0.042	-	-	0.055	0.055
24	0.042	0.042	-	-	0.055	0.057
25	0.041	0.043	-	-	0.057	0.059
26	0.041	0.043	-	-	0.058	0.061
27	0.041	0.043	-	-	0.059	0.062
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

[1] Vintage weight in the last year (for example, year 27 for the 2018-based CIPI) is applied to the most recent data point and prior vintage weights are applied going back in time. For example, year 27 vintage weight would be applied to the 2022q3 fixed price proxy level, year 26 vintage weight would be applied to the 2021q3 fixed price proxy level, etc.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table IV–10 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found under the following CMS website link: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

As noted, we did not receive any public comments on our methodology for deriving the proposed 2018-based CIPI. Accordingly, in this final rule and for the reasons discussed, we are finalizing the 2018-based CIPI as proposed. Table IV–11 in this section of this final rule compares both the historical and forecasted percent changes in the 2014-based CIPI and the 2018-based CIPI based on IGI's second quarter 2021 forecast with historical data through first quarter 2021.

TABLE IV-11.—COMPARISON OF 2014-BASED AND 2018-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2017 THROUGH FY 2024

Fiscal Year	CIPI, 2014-Based	CIPI, 2018-Based
Historical Data:		
FY 2017	1.1	1.0
FY 2018	1.2	1.1
FY 2019	1.4	1.3
FY 2020	1.2	1.2
Average FYs 2017-2020	1.2	1.2
Forecast:		
FY 2021	1.0	1.0
FY 2022	1.1	1.1
FY 2023	1.2	1.1
FY 2024	1.3	1.2
Average FYs 2021-2024	1.2	1.1

Source: IHS Global, Inc., 2nd quarter 2021 forecast.

IHS Global, Inc. forecasts a 1.1 percent increase in the 2018-based CIPI for FY 2022, as shown in Table IV–11. The underlying vintage-weighted price increases for depreciation (including building and fixed equipment and movable equipment) and interest (including government/nonprofit and for-profit) based on the 2018-based CIPI are included in Table IV–12.

TABLE IV-12.— 2018-BASED CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND DEPRECIATION AND INTEREST COMPONENTS-- FYs 2017 THROUGH 2024

Fiscal Year	Total	Depreciation	Interest
Historical Data:			
FY 2017	1.0	1.6	-2.4
FY 2018	1.1	1.6	-2.2
FY 2019	1.3	1.8	-1.9
FY 2020	1.2	1.8	-2.9
Forecast:			
FY 2021	1.0	1.7	-3.6
FY 2022	1.1	1.7	-3.2
FY 2023	1.1	1.7	-2.8
FY 2024	1.2	1.6	-2.6

Source: IHS Global, Inc., 2nd quarter 2021 forecast.

Rebasing the CIPI from 2014 to 2018 did not have an impact on the percent change in the forecasted update for FY 2022 when rounded, as shown in Table IV–11.

V. Other Decisions and Changes to the IPPS for Operating Costs

A. Changes in the Inpatient Hospital Update for FY 2022 (§ 412.64(d))

1. FY 2022 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2022, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2021. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and

10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2022 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.
- An adjustment based on changes in economy-wide multifactor productivity (MFP) (the productivity adjustment).

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

We note, in compliance with section 404 of the MMA, in the proposed rule, we proposed to replace the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets for FY 2022.

We proposed to base the proposed FY 2022 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2020, which was estimated to be 2.5 percent. We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket update and the productivity adjustment), we would use such data, if appropriate, to determine the FY 2022 market basket update and the productivity adjustment in this final rule. We received public comments regarding the rebasing and revising of the IPPS operating market basket and refer readers to section IV.B. of this final rule for a complete discussion on the rebasing and revising of the market basket. In section IV.B., we are finalizing our proposals without modification and, therefore, are using the finalized rebased and revised 2018-based IPPS market basket rate-of increase for FY 2022.

Based on more recent data available for this FY 2022 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2021 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2021), we estimate that the FY 2022 market basket update used to determine the applicable percentage increase for the IPPS is 2.7 percent.

For FY 2022, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount, as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. A complete description of the MFP projection methodology is available on the CMS website at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* We note that beginning with this FY 2022 final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology.

For FY 2022, we proposed a productivity adjustment of 0.2 percentage point. Similar to the market basket update, for the proposed rule, we used IGI's fourth quarter 2020 forecast of MFP to compute the proposed FY 2022 productivity adjustment. As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2022 market basket update and the productivity adjustment for this final rule. Based on more recent data available for this FY 2022 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2021 forecast), the current estimate of the productivity adjustment for FY 2022 is 0.7 percentage point.

We did not receive any public comments on our proposal to use more recent available data to determine the final market basket update and the productivity adjustment. Therefore, for this final rule, we are finalizing a market basket update of 2.7 percent and a productivity adjustment of 0.7 percentage point based on the more recent available data.

Based on these more recent data available, for this final rule, we have determined four applicable percentage increases to the standardized amount for FY 2022, as specified in the following table:

FY 2022 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2022	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.675	-0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.025	0	-2.025
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.7	-0.7	-0.7	-0.7
Applicable Percentage Increase Applied to Standardized Amount	**2.0**	**-0.025**	**1.325**	**-0.7**

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In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less a productivity adjustment. (As previously noted, section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. (Under current law, the MDH program is effective for discharges on or before September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).)

For FY 2022, we proposed the following updates to the hospital-specific rates applicable to SCHs and MDHs: a proposed update of 2.3 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.425 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of 1.675 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and a proposed update of -0.2 percent for a hospital that fails to submit quality data and is not an meaningful EHR user. As noted previously, for the FY 2022 IPPS/LTCH PPS proposed rule, we used IGI's fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket update with historical data through third quarter 2020. Similarly, we used IGI's fourth quarter 2020 forecast of the productivity adjustment. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket update and the productivity adjustment), we would use such data, if appropriate, to determine the update in the final rule.

We did not receive any public comments on our proposal. Therefore, we are finalizing the proposal to determine the update to the hospital specific rates for SCHs and MDHs in this final rule using the more recent available data, as previously discussed.

For this final rule, based on more recent available data, we are finalizing the following updates to the hospital specific rates applicable to SCHs and MDHs: An update of 2.0 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 1.325 percent for a hospital that fails to submit quality data and is a meaningful EHR user; an update of -0.025 percent for a hospital that submits quality data and is not a meaningful EHR user; and an update of -0.7 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. FY 2022 Puerto Rico Hospital Update

Section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that

is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

For FY 2022, consistent with section 1886(b)(3)(B) of the Act, as amended by section 602 of Public Law 114–113, we are setting the applicable percentage increase for Puerto Rico hospitals by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS for Puerto Rico hospitals will be equal to the rate of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a 33⅓ percent reduction to three-fourths of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for Puerto Rico hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to the productivity adjustment at section 1886(b)(3)(B)(xi) of the Act. As noted previously, section 1886(b)(3)(B)(xi) of the Act states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

Based on IGI's fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket update with historical data through third quarter 2020, in the FY 2022 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we proposed a market basket update of 2.5 percent and a productivity adjustment of 0.2 percent. Therefore, for FY 2022, depending on whether a Puerto Rico hospital is a meaningful EHR user, we stated that there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2022 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we proposed an applicable percentage increase to the FY 2022 operating standardized amount of 2.3 percent (that is, the FY 2022 estimate of the proposed market basket rate-of-increase of 2.5 percent less an adjustment of 0.2 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we proposed an applicable percentage increase to the operating standardized amount of 1.675 percent (that is, the FY 2022 estimate of the proposed market basket rate-of-increase of 2.5 percent, less an adjustment of 0.625 percentage point (the proposed market basket rate of-increase of 2.5 percent × 0.75)/3) for failure to be a meaningful EHR user, less an adjustment of 0.2 percentage point for the proposed productivity adjustment.

As noted previously, we proposed that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2022 market basket update and the productivity adjustment for the FY 2022 IPPS/LTCH PPS final rule.

We did not receive any public comment on our proposal with respect to the Puerto Rico hospital update.

As previously discussed in section V.A.1, based on more recent data available for this FY 2022 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2021 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2021), we estimate that the FY 2022 market basket update used to determine the applicable percentage increase for the IPPS is 2.7 percent and a productivity adjustment of 0.7 percent. Therefore, in accordance with section 1886(b)(3)(B) of the Act, for this final rule, for Puerto Rico hospitals the more recent update of the market basket update is 2.7 percent and a productivity adjustment of 0.7 percent. For FY 2022, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we determined the following applicable percentage increases to the standardized amount for FY 2022 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, an applicable percentage increase to the FY 2022 operating standardized amount of 2.0 percent (that is, the FY 2022 estimate of the market basket rate-of-increase of 2.7 percent less an adjustment of 0.7 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of 1.325 percent (that is, the FY 2022 estimate of the market basket rate-of-increase of 2.7 percent, less an adjustment of 0.675 percentage point (the market basket rate of-increase of 2.7 percent × 0.75)/3) for failure to be a meaningful EHR user, less an adjustment of 0.7 percentage point for the productivity adjustment.

B. Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we

stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Amendment to Timeframe used for Case-Mix Index (CMI) Under § 412.96(c)(1) and § 412.96(h) and Discharges Under § 412.96(i) for RRC Classification

a. Case-Mix Index (CMI)

As previously noted, in addition to meeting other criteria, to qualify for initial RRC status for cost reporting periods beginning on or after October 1 of a given fiscal year, under § 412.96(c)(1), a hospital must meet the minimum case-mix index (CMI) value during the most recent Federal fiscal year that ended at least one year prior to the beginning of the cost reporting period for which the hospital is seeking RRC status. We typically use the data from the Federal fiscal year that is two years prior to the Federal fiscal year for which a hospital is seeking RRC status to compute the national and regional median CMI values, as these are generally the best available data at the time of the development of the proposed and final rules. For example, in the FY 2021 IPPS/LTCH PPS final rule, we calculated the national and regional median CMIs using discharges occurring during FY 2019 (October 1, 2018 through September 30, 2019).

However, as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25437), the best available data to use for certain purposes of this FY 2022 rulemaking may not be the FY 2020 data that we would ordinarily use, due to the impact of the COVID–19 PHE. We stated in the proposed rule that we believe that the differences in utilization for certain types of services in FY 2020 as compared to what would have been expected in the absence of the PHE also affects the calculation of the CMI values used for purposes of determining RRC status. We noted that the CMI values calculated using the FY 2020 data are significantly different from the CMI values calculated using the FY 2019 data. As such, while we would normally have proposed to use data from FY 2020 to calculate CMI values, we instead proposed to use values that are based on discharges occurring during FY 2019 (October 1, 2018 through September 30, 2019), and include claims posted to CMS' records through March 2020. We made available for public comment the CMI values calculated using the FY 2020 data that we would ordinarily propose to use (86 FR 25784).

Accordingly, we proposed to amend § 412.96(c)(1) with regard to the data to be used in identifying the CMI value for an individual hospital that is used to determine whether the hospital meets the CMI criteria for purposes for RRC classification. Specifically, we proposed to amend § 412.96(c)(1) to indicate that the individual hospital's CMI value for discharges during the same Federal fiscal year used to compute the national and regional CMI values is used for purposes of determining whether a hospital qualifies for RRC classification. We also proposed to amend § 412.96(h)(1) to provide for the use of the best available data rather than the latest available data in calculating the national and regional CMI criteria.

Commenters supported these proposals. We are therefore finalizing these proposals, including the proposed amendments, without modification.

b. Discharges

As previously noted, in addition to meeting other criteria, to qualify for initial RRC status for cost reporting periods beginning on or after October 1 of a given fiscal year, under § 412.96(c)(2), a hospital must meet the minimum number of discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges. We typically use the cost reporting periods that are 3 years prior to the fiscal year for which a hospital is seeking RRC status to compute the regional median discharges, as these are generally the latest cost report data available at the time of the development of the proposed and final rules. For example, in the FY 2021 IPPS/LTCH PPS final rule, we calculated the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2018.

However, as discussed in section I.F. of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25437), the best available data to use for certain purposes of this FY 2022 rulemaking may not be the FY 2019 cost report data that we would ordinarily use, due to the impact of the COVID–19 PHE. We stated that we believe that the differences in utilization for certain types of services in FY 2019 cost reporting periods that spanned the PHE as compared to what would have been expected in the absence of the PHE also affects the calculation of the regional median discharges used for purposes of determining RRC status. We noted that the regional median discharges calculated using the FY 2019 cost report data are different from the regional median discharges values calculated using the FY 2018 data. As such, while we ordinarily would have proposed to calculate the regional median discharges based on cost reports with cost reporting periods beginning in FY 2019 (October 1, 2018 through September 30, 2019), we instead proposed to calculate the regional median discharges based on cost reports with cost reporting periods beginning in FY 2018 (October 1, 2017 through September 30, 2018). We made available for public comment the regional median discharges calculated using FY 2019 cost report data that we would ordinarily propose to use (86 FR 25784).

Accordingly, we proposed to amend the regulations at § 412.96(i)(1) and (2), which describe the methodology for calculating the number of discharges criteria, to provide for the use of the best available data rather than the latest available or most recent data when calculating the regional discharges for RRC classification.

Commenters supported these proposals. We are therefore finalizing these proposals, including the proposed amendments, without modification.

2. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii), in conjunction with the amendment to provide for the use of the best available data rather than the use of the latest available data. The national median CMI value for FY 2022 is based on the CMI values of all urban hospitals nationwide, and the regional median CMI values for FY 2022 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). For the reasons discussed previously, the values are based on discharges occurring during FY 2019 (October 1, 2018 through September 30, 2019), and include claims posted to CMS' records through March 2020.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25438), we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2021, they must have a CMI value for FY 2019 that is at least—

- 1.7049 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region were set forth in a table in the proposed rule (86 FR 25439). We stated in the proposed rule that we may update the proposed CMI values in the FY 2022 final rule to reflect finalized policies for FY 2022, including the best available data.

Commenters supported these proposals. Therefore, based on the best available data (FY 2019 claims received through March 2020), in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2021, they must have a CMI value for FY 2019 that is at least:

- 1.7049 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The final CMI values by region are set forth in the following table.

Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.4447
2. Middle Atlantic (PA, NJ, NY)	1.5005
3. East North Central (IL, IN, MI, OH, WI)	1.60875
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.62455
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5777
6. East South Central (AL, KY, MS, TN)	1.54085
7. West South Central (AR, LA, OK, TX)	1.74375
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7833
9. Pacific (AK, CA, HI, OR, WA)	1.6913

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

3. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25438), for FY 2022, consistent with our proposed amendments to § 412.96(i)(1) and (2) to provide for the use of the best available data rather than the latest available or most recent data, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2018 (that is, October 1, 2017 through September 30, 2018). Therefore, we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2021, must have, as the number of discharges for its cost reporting period that began during FY 2018, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2022 IPPS/LTCH PPS proposed rule at 86 FR 25439). We note, that for this final rule, we calculated the median number of discharges for urban hospitals using the latest update of FY 2018 HCRIS data. There was no change in the median number of discharges from the proposed rule. Commenters supported these proposals.

Therefore, based on the best available discharge data at this time, that is, for cost reporting periods that began during FY 2018, the final median number of discharges for urban hospitals by census region are set forth in the following table.

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,692
2. Middle Atlantic (PA, NJ, NY)	10,276
3. East North Central (IL, IN, MI, OH, WI)	8,787
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,647
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,616
6. East South Central (AL, KY, MS, TN)	9,134
7. West South Central (AR, LA, OK, TX)	6,288
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,774
9. Pacific (AK, CA, HI, OR, WA)	9,063

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this final rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

C. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 Through 2022. (Section 50204 of Pub. L. 115–123 also extended prior changes to the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals through FY 2018.) Currently, the low-volume hospital qualifying criteria provide that a hospital must have fewer 3,800 total discharges during the fiscal year, and the hospital must be located more than 15 road miles from the nearest ''subsection (d)'' hospital. These criteria will remain in effect through FY 2022. Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. Therefore, in order for a hospital to continue to qualify as a low-volume hospital on or after October 1, 2022, it must have fewer than 200 total discharges during the fiscal year and be located more than 25 road miles from the nearest ''subsection (d)'' hospital (see § 412.101(b)(2)(i)). (For additional information on the low-volume hospital payment adjustment prior to FY 2018, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56941 through 56943). For additional information on the low-volume hospital payment adjustment for FY 2018, we refer readers to the FY 2018 IPPS notice (CMS–1677–N) that appeared in the April 26, 2018 **Federal Register** (83 FR 18301 through 18308).)

2. Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FYs 2019 Through 2022

As discussed earlier, section 50204 of the Bipartisan Budget Act of 2018 further modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. Specifically, the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act were amended to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 1886(d)(12)(D) of the Act was also amended to provide that, for discharges occurring in FYs 2019 through 2022, the Secretary shall determine the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), to implement this requirement, we specified a continuous, linear sliding scale formula to determine the low-volume hospital payment adjustment for FYs 2019 through 2022 that is similar to the continuous, linear sliding scale formula used to determine the low-volume hospital payment adjustment originally established by the Affordable Care Act and implemented in the regulations at § 412.101(c)(2)(ii) in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. As such, for qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment for FYs 2019

through 2022 is calculated using the following formula:

Low-Volume Hospital Payment Adjustment = 0.25–[0.25/3300] × (number of total discharges − 500) = (95/330) − (number of total discharges/13,200).

For this purpose, we specified that the ''number of total discharges'' is determined as total discharges, which includes Medicare and non-Medicare discharges during the fiscal year, based on the hospital's most recently submitted cost report. The low-volume hospital payment adjustment for FYs 2019 through 2022 is set forth in the regulations at 42 CFR 412.101(c)(3).

3. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking (for example, the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401)), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and (iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

As also discussed in the FY 2019 IPPS/LTCH PPS final rule, in addition to the discharge criterion, for FY 2019 and for subsequent fiscal years, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in § 412.101(b)(2)(i) or (iii) for the fiscal year. Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2022, as was the case for FYs 2019, 2020 and 2021, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year).[760] For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2022, we proposed that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Consistent with historical practice, for FY 2022, we proposed that a hospital's written request must be received by its MAC no later than September 1, 2021 in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2021. If a hospital's written request for low-volume hospital status for FY 2022 is received after September 1, 2021, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2022 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination. We noted that this proposal is generally consistent with the process for requesting and obtaining the low-volume hospital payment adjustment for FY 2021 (85 FR 58802 through 58803).[761]

Under this process, a hospital receiving the low-volume hospital payment adjustment for FY 2021 may continue to receive a low-volume hospital payment adjustment for FY 2022 without reapplying if it continues to meet the applicable mileage and discharge criteria (which, as discussed previously, are the same qualifying criteria that apply for FY 2021). In this case, a hospital's request can include a

[760] We note that for FY 2021, we established a deadline of September 15, 2020 for receipt of a hospital's written request its MAC in order for the low-volume hospital payment adjustment to be applied to payments for a hospital's discharges beginning on or after October 1, 2020, as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58803).

[761] As noted, CMS established a deadline of September 15, 2020 for receipt of the hospital's written request for FY 2021, as discussed in the FY 2021 IPPS/LTCH PPS final rule.

verification statement that it continues to meet the mileage criterion applicable for FY 2022. (Determination of meeting the discharge criterion is discussed earlier in this section.) We note that a hospital must continue to meet the applicable qualifying criteria as a low-volume hospital (that is, the hospital must meet the applicable discharge criterion and mileage criterion for the fiscal year) in order to receive the payment adjustment in that fiscal year; that is, low-volume hospital status is not based on a ''one-time'' qualification (75 FR 50238 through 50275). Consistent with historical policy, a hospital must submit its request, including this written verification, for each fiscal year for which it seeks to receive the low-volume hospital payment adjustment, and in accordance with the timeline described earlier.

Comment: We received comments expressing continued support of the low-volume hospital payment adjustment changes included in the Bipartisan Budget Act of 2018.

Response: We appreciate commenters' support.

We received no public comments on our proposals related to the process for requesting and obtaining the low-volume hospital payment adjustment, therefore, we are finalizing our proposals as previously described, without modification.

D. Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2022, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2022 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

We did not receive any comments regarding the IME adjustment factor, which, as noted earlier, is statutorily required. Accordingly, for discharges occurring during FY 2022, the IME formula multiplier is 1.35.

E. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2022 (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: The ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this final rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

Section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress.

We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus a statutory adjustment of 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on a hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. For the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to determine eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year using the best available data, as discussed in section V.E. of the preamble of the proposed rule. In the proposed rule, we also referred readers to a discussion of the inpatient Provider Specific File in section II.A.4 of the Addendum of the proposed rule (86 FR 25725). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25443 and 25444), we discussed our specific policies regarding eligibility to receive empirically justified Medicare DSH payments and uncompensated care payments for FY 2022 with respect to the following hospitals:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which

began on January 1, 2019. Under the Maryland TCOC Model, Maryland hospitals will not be paid under the IPPS in FY 2022, and will be ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.

• *Sole community hospitals* (*SCHs) that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).

• *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017, through September 30, 2022. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments as we do for all other IPPS hospitals. Due to the extension of the MDH program, MDHs will continue to be paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years. Accordingly, we proposed to continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the best available data). Our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we will calculate a Factor 3 and an uncompensated care payment amount for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator of Factor 3 of the uncompensated care payment methodology will be based only on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.

• *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model starting October 1, 2018,* will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

• *IPPS hospitals that participate in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In the FY 2022 IPPS/LTCH PPS proposed rule, we referred readers to the interim final rule with request for comments that appeared in the November 6, 2020 **Federal Register** for a discussion of the Model (85 FR 71167 through 71173). In that interim final rule, we extended the Model's Performance Year 5 to September 30, 2021. In a subsequent final rule that appeared in the May 3, 2021 **Federal Register** (86 FR 23496), we further extended the Model for an additional three performance years. The Model's Performance Year 8 will end on December 31, 2024.

• *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Public Law 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Pub. L. 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. The Consolidated Appropriations Act of 2020 (Pub. L. 116–260) amended section 410A of Pub. L. 108–173 to extend the Rural Community Hospital Demonstration Program for an additional 5-year period. At the time of issuance of the proposed rule, we believed 27 hospitals might participate in the demonstration program at the start of FY 2022. At the time of development of this final rule, there are 26 hospitals that will be participating in the demonstration program in FY 2022. Under the payment methodology that applies during the third 5-year extension period for the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are also excluded from receiving interim and final uncompensated care payments.

We received no comments on our proposal to continue the policy of using the best available data regarding a hospital's estimated DSH status for purposes of determining eligibility for interim uncompensated care payments for FY 2022. Therefore, we are finalizing as proposed without modifications. Our final determination of a hospital's eligibility for uncompensated care payments will continue to be based on the hospital's actual DSH status at cost report settlement for that payment year.

We received public comments that were outside the scope of this proposed rule. Specifically, commenters expressed concerns related to Section 340B eligibility. Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising the Medicare Administrative Contractors (MACs) to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html*.

4. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. In this section of this final rule, we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2021, and the policies we are finalizing for FY 2022.

a. Calculation of Factor 1 for FY 2022

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) The aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25444 through 25447), in order to determine Factor 1 in the uncompensated care payment formula for FY 2022, we proposed to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. Consistent with the policy that has applied in previous years, we proposed that these estimates will not be revised or updated subsequent to the publication of our final projections in this FY 2022 IPPS/LTCH PPS final rule.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2022 (Medicare DSH payments prior to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments after application of section 1886(r)(1) of the Act), for this final rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary (OACT) using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File. The determination of the amount of DSH payments is partially based on OACT's Part A benefits projection model. One of the results of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2019 through FY 2022 are discussed in the table titled ''Factors Applied for FY 2019 through FY 2022 to Estimate Medicare DSH Expenditures Using FY 2018 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of the FY 2022 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's January 2021 Medicare DSH estimates, which were based on data from the September 2020 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2021 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2021 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the January 2021 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified

Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's January 2021 Medicare DSH estimates. The 27 hospitals that were anticipated to participate in the Rural Community Hospital Demonstration Program in FY 2022 were also excluded from these estimates, because under the payment methodology that applies during the third 5-year extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or interim and final uncompensated care payments.

For the proposed rule, using the data sources as previously discussed, the Office of the Actuary's January 2021 estimate of Medicare DSH payments for FY 2022 without regard to the application of section 1886(r)(1) of the Act, was approximately $14.098 billion. Therefore, also based on the January 2021 estimate, the estimate of empirically justified Medicare DSH payments for FY 2022, with the application of section 1886(r)(1) of the Act, was approximately $3.524 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2022). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two OACT estimates. Therefore, in the proposed rule, we proposed that Factor 1 for FY 2022 would be $ 10,573,368,841.28, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2021 ($14,097,825,121.71 minus $3,524,456,280.43). In the FY 2022 IPPS/LTCH PPS proposed rule, we noted that consistent with our approach in previous rulemakings, OACT intended to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for this FY 2022 IPPS/LTCH PPS final rule.

As we noted in the FY 2022 IPPS/LTCH PPS proposed rule, the Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for final rules are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget*. Consistent with historical practice, we indicated that we expected the Midsession Review would have updated economic assumptions and actuarial analysis, which would be used for the development of Factor 1 estimates in the final rule. At the time of developing this final rule, the Midsession Review was not yet available, therefore the estimates in this final rule are generally consistent with the economic assumptions and actuarial analysis used to develop the forthcoming Medicare Trustees Report.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html?redirect=/reportstrustfunds/* under ''Downloads.'' We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections. (available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/MedicaidReport*).

Comment: As in previous years, a common concern and/or request expressed by some commenters was the need for greater transparency in the methodology used by CMS and OACT to calculate Factor 1; several commenters specifically requested that a detailed description of the methodology and the data behind the assumptions be made public. Commenters requested that this information be provided in advance of the publication of the final rule and in the IPPS proposed rule each year going forward, in order that the data be available to replicate CMS' DSH calculation and comment sufficiently in future years. Similarly, another commenter requested that CMS provide hospitals and other stakeholders with a supplementary table and additional commentary on the year-to-year changes from the FY 2021 final rule to the FY 2022 proposed rule for the variables that comprise the ''Other'' factor. The commenter requested that CMS provide this information and allow for a brief supplemental comment period prior to finalizing the FY 2022 rule. The commenter stated that if CMS is unable to provide additional information in such a manner, then it should use the ''Other'' factor from the FY 2021 final rule for the FY 2022 final rule. Another commenter suggested that the methodology and assumptions in projecting DSH costs be reviewed by independent experts.

Additionally, a commenter asserted that the lack of opportunity afforded to hospitals to review the data used in rulemaking is in violation of the Administrative Procedure Act and expressed concerns about the lack of transparency in how Factor 1 is calculated, arguing that hospitals cannot meaningfully comment on the methodology given the lack of details. In particular, this commenter asserted that the proposed rule neither explained the assumption that Medicaid expansion would draw enrollees who are healthier than the average Medicaid beneficiary and, by extension, would have fewer hospital visits, nor described the data CMS used in making this assumption.

Response: We thank the commenters for their input. We disagree with commenters' assertion regarding the lack of transparency with respect to the methodology and assumptions used in the calculation of Factor 1. As explained in the FY 2022 IPPS/LTCH PPS proposed rule, and in this section of this final rule, we have been and continue to be transparent about the methodology and data used to estimate Factor 1. Regarding the comments referencing the Administrative Procedure Act, we note that under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2022 IPPS/LTCH PPS proposed rule did include a detailed discussion of our proposed Factor 1 methodology and the data sources that would be used in making our final estimate. Accordingly, we believe commenters were able to meaningfully comment on our proposed estimate of Factor 1.

To provide context, we note that Factor 1 is not estimated in isolation from other projections made by OACT. The Factor 1 estimates for proposed

rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates in this final rule are generally consistent with those used for the forthcoming ''2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' which will be made available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html* under ''Downloads.'' For additional information on the development of the President's Budget, we refer readers to the OMB website at: *https://www.whitehouse.gov/omb/budget*.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the forthcoming 2021 Medicare Trustees Report. We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2018.pdf* for a discussion of general issues regarding Medicaid projections. Additionally, as described in more detail later in this section, in the FY 2022 IPPS/LTCH PPS proposed rule, we included information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's estimate of Factor 1. In summary, we indicated the historical HCRIS data update OACT used to identify Medicare DSH payments, we explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provided the components of all update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also included a description of the ''Other'' and ''Discharges'' assumptions, as well as additional information regarding how we address the Medicaid and CHIP expansion.

Regarding the commenters' requests for further information on our assumptions regarding the effect of Medicaid expansion on the Medicaid population, we provide a discussion of more recent estimates and assumptions regarding Medicaid expansion as part of the discussion of the final Factor 1 for FY 2022, which also incorporates the estimated impact of the COVID–19 pandemic.

Comment: Many commenters requested that CMS calculate estimated DSH payments for purposes of Factor 1 without adjusting for the impact of the COVID–19 PHE, which the commenters believed would align with other CMS proposals regarding COVID–19 PHE data (for example, IPPS and LTCH ratesetting proposal to use FY 2019 claims data). Many other commenters urged CMS to consider freezing data prior to the PHE for purposes of the Factor 1 methodology. Commenters stated that excluding PHE impacts from Factor 1 methodology would allow more time to evaluate national Medicare uncompensated care funding and the ongoing impacts of the COVID–19 pandemic on beneficiaries and hospitals providing care.

Some commenters requested that CMS revisit the estimate for Factor 1 and provide greater transparency regarding its calculations, as they disagree with CMS' proposed 7.1% decrease from FY 2021. For example, according to a commenter, the September 2020 extract of HCRIS cost report files used in OACT's Factor 1 methodology for purposes of the proposed rule reflected providers that had minimal COVID–19 data (that is, March 2020 and earlier data), and this commenter requested that CMS revisit the estimates and provide greater transparency. Some commenters believed that CMS should work to mitigate the effect of the pandemic and associated anomalies in FY 2020 and 2021 cost report data that will have an adverse on uncompensated care payments in future years.

Many commenters asserted that there was a much higher Medicaid enrollment in 2020–2021 during the pandemic than CMS estimated for purposes of Factor 1. A commenter referred to a New York Times article from June 21, 2021, which indicated that nearly 10 million Americans enrolled in Medicaid and CHIP during the pandemic. This same commenter also disagreed with OACT's assumption of lower utilization by newly eligible Medicaid enrollees, and the commenter believed that lower utilization was caused by patients' reluctance to seek care and instead opting to delay care and elective procedures during the PHE. The commenter urged CMS to be transparent in how the ''Other'' factor was determined and share the data behind its assumptions.

Another commenter cited survey data from the Kaiser Family Foundation that show a 7.7 million (or 10.8%) increase in Medicaid/CHIP enrollment from February 2020 to November 2020. Further, they noted that the 0.9 percentage point increase in the estimated increase in Medicaid enrollment for FY 2021 (FY 2021 Final Rule, 0.3%, FY 2022 Proposed Rule, 1.2%) does not explain the reduction in the estimate of the ''other'' factor for FY 2021—as such they can only infer there was a significant decrease in one or more of the ''other'' variables that negated the increased estimate of Medicaid eligibility. To this end, commenters requested additional explanation for the proposed decrease to the ''other'' factor for FY 2021. Some commenters believed the 20% add-on to payments for COVID–10 discharges would have contributed to an increase in the ''other'' factor, rather than a decrease.

Many commenters questioned the proposed rule's estimate of the ''Discharges'' factor, in particular. Some commenters referenced a Kaufman Hall study, which showed that the year-to-date adjusted discharges were up 5.9% and the year-over-year and adjusted discharges were up 66.4% as of April 2021. A commenter also referred to national utilization data from Strata Decision Technology and stated that total inpatient admissions began to increase starting in February 2021, consistent with declines in COVID–19 inpatient volumes. The commenter stated that, although, FY 2021 volumes will remain lower than historic, pre-pandemic levels, the trends indicate that FY 2021 volumes will continue to increase. These comments urged CMS to carefully monitor changes in discharge volume when estimating Factor 1 for FY 2022. A commenter urged CMS to use a later update to the claims data consistent with the data that CMS otherwise uses to model IPPS impacts and set relative weights in a typical year. While some commenters believed that using the latest available data when finalizing Factor 1 might capture more of the increases in utilization that are

anticipated for FY 2022, a commenter noted that the use of more recent data alone may not fully account for the increase in discharges during the second half of FY 2021. Another commenter noted that OACT's estimate of the ''Discharges'' factor was based on preliminary FY 2021 claims data, given the lack of time for ''claims run out.''

Additionally, commenters requested further explanation regarding the estimate of the ''Other'' factor used to estimate Medicare DSH payments, and in particular an analysis of the difference between total inpatient hospital discharges and IPPS discharges, along with the agency's quantitative analysis of the interplay between the various factors grouped together as ''Other'' factors impacting estimated DSH payments. Specifically, commenters requested that OACT address the expected increase in IPPS discharges as a percentage of total inpatient hospital discharges in the latter half of FY 2021 and the impact of these FY 2021 data trends on the ''Other'' factors impacting estimated DSH Medicare payments for FY 2021. A commenter mentioned that, according to their own analysis, total inpatient discharges and IPPS discharges have changed in a similar manner. Another commenter stated that CMS has not adequately measured the impact of the shift away from direct patient care to telehealth care, in terms of hospital volumes and payments. A commenter also suggested that CMS use OACT's estimate of FY 2021 Medicare discharges from the FY 2021 Final Rule to estimate discharges for FY 2022 ''Discharge'' factor. Similarly, another commenter suggested that CMS use estimates of the ''Other'' factor variables from the FY 2021 Final Rule for FY 2022, because of the commenter's concerns with the transparency of the Factor 1 estimates in the FY 2022 proposed rule.

Other commenters believed that as vaccination rates increase and infection rates decline, people can be expected to begin addressing their deferred medical needs in the year ahead. As a result, these commenters indicated that the historical data used to estimate inpatient hospital utilization among Medicare and Medicaid-covered individuals understates the actual amount of inpatient care hospitals are likely to provide in the coming year.

Response: We thank the commenters for their input on impact projections, such as the impact on Medicaid enrollment from the COVID–19 PHE, and have taken into consideration the concerns commenters have raised in making our projection of Factor 1 for this FY 2022 IPPS/LTCH PPS final rule. In updating our estimate of Factor 1, we considered, as appropriate, the same set of factors that we used in the proposed rule, as updated to account for the unique economic situation presented by the COVID–19 PHE. We note that the estimated increases in new Medicaid enrollees used for the ''Other'' factor are generally consistent with the updated Factor 2 calculation described in the next section. The updated estimates for the ''Discharges'' and ''Case Mix'' factors incorporate the latest estimates from OACT of the impact of COVID–19 on the Medicare program. We provide further details on the updated Factor 1 estimate and data sources as part of the discussion of the final Factor 1 estimate for FY 2022 in this section of the rule.

Regarding the comments requesting further explanation of the difference between total inpatient hospital discharges and IPPS discharges, we note that the ''Discharges'' factor used to estimate Medicare DSH expenditures relates to IPPS discharges for DSH eligible hospitals. As discussed further in this section, the ''Other'' factor includes an estimate of the effect of the difference between total inpatient hospital discharges compared to discharges at IPPS hospitals (particularly those in DSH hospitals). Based on the data sources and modeling that are used for Factor 1, we do not break down this effect to the level that commenters are requesting additional information. In other words, we do not project each individual effect that is part of ''Other'' factor. We note that the OACT's FY 2022 estimate of 1.0038 for the ''Other'' factor is an increase relative to the FY 2021 estimate of 0.9662 for the ''Other'' factor.

Regarding the comments requesting that we exclude and/or mitigate the impacts of the pandemic when estimating Factor 1 for FY 2022, we note that the statute specifies that Factor 1 is based on the amount of disproportionate share payments that would otherwise be made to a subsection (d) hospital for the fiscal year. As discussed further in this section, OACT's estimates of Medicare DSH payments used in the development of Factor 1, reflect the estimated impact of the COVID–19 pandemic on DSH payments. We do not believe that excluding and/or mitigating the impact of the pandemic through adjustments to Factor 1 calculation would be consistent with the statute.

After consideration of the public comments we received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2022. We discuss the resulting Factor 1 amount for FY 2022 in this section. For this final rule, OACT used the most recently submitted Medicare cost report data from the March 31, 2021 update of HCRIS to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File published in conjunction with the publication of the FY 2021 IPPS/LTCH PPS final rule and applied update factors and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The July 2021 OACT estimate for Medicare DSH payments for FY 2022, without regard to the application of section 1886(r)(1) of the Act, was approximately $13.985 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate. Therefore, based on the July 2021 estimate, the estimate of empirically justified Medicare DSH payments for FY 2022, with the application of section 1886(r)(1) of the Act, was approximately $3.496 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2022). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two OACT estimates. Therefore, the final Factor 1 for FY 2022 is $10,488,564,546.74, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2022 ($13,984,752,728.99 minus $3,496,188,182.25). OACT's final estimates for FY 2022 began with a baseline of $13.882 billion in Medicare DSH expenditures for FY 2018. The following table shows the factors applied to update this baseline through the current estimate for FY 2022:

Factors Applied for FY 2019 through FY 2022 to Estimate Medicare DSH Expenditures Using FY 2018 Baseline						
FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)*
2019	1.0185	0.97	1.009	1.0176	1.0144	14.082
2020	1.031	0.857	1.038	0.9912	0.9091	12.801
2021	1.029	1.013	1.029	0.9662	1.0364	13.267
2022	1.025	1.059	0.9675	1.00375	1.0541	13.985

*Rounded.

In this table, the discharges column shows the changes in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FY 2019 and FY 2020 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. The discharge figure for FY 2021 is based on preliminary data. The discharge figure for FY 2022 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The discharge figures for FY 2020 to FY 2022 reflect the estimated impact of the COVID–19 pandemic. The case-mix column shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for FY 2019 and FY 2020 are based on actual data adjusted by a completion factor. The case-mix figure for FY 2021 is based on preliminary data. The case-mix factor figures for FY 2020 and FY 2021 have been adjusted for the estimated impact of the COVID–19 pandemic. The FY 2022 increase is an estimate based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy and the 20 percent add-on for COVID–19 discharges). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act. The factor for Medicaid expansion was developed using public information and statements for each State regarding its intent to implement the expansion. Based on the information available at the time of development of this final rule, it is assumed that approximately 55 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2018, 2019, and 2020 resided in States that had elected to expand Medicaid eligibility, and approximately 60 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2021 and thereafter, resided in States that had elected to expand Medicaid eligibility. In the future, these assumptions may change based on actual participation by States. The ''Other'' column also includes the estimated impacts on Medicaid enrollment due to the COVID–19 pandemic. In the proposed rule, we noted that, based on the most recent available data at that time, it was estimated that Medicaid enrollment increased by 2.9 percent in FY 2020 and would increase by an additional 1.2 percent in FY 2021. For this final rule, we have used updated assumptions of Medicaid enrollment. For a further discussion, we refer readers to the OACT's Memorandum on Factor 1, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh*.

For a discussion of general issues regarding Medicaid projections, we refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2017.pdf*. We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services. Specifically, based on the most recent available data, OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 78 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25446), we noted that this is an updated assumption based on more recent data compared to the data available at the time of the FY 2021 IPPS/LTCH PPS final rule. This same assumption was used for the new Medicaid beneficiaries who enrolled in 2020 and thereafter due to the COVID–19 pandemic. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

The following table shows the factors that are included in the ''Update'' column of the previous table:

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Productivity Adjustment	Documentation and Coding	Total Update Percentage
2019	2.9	-0.75	-0.8	0.5	1.85
2020	3.0	0	-0.4	0.5	3.1
2021	2.4	0	0	0.5	2.9
2022	2.7	0	-0.7	0.5	2.5

Note: All numbers are from the inpatient hospital updates for the applicable year, except for the FY 2022 percentages, which are based on the most recent forecast. We refer readers to section V.A. of the preamble of this final rule for a complete discussion of the changes in the inpatient hospital update for FY 2022, including a discussion of the productivity adjustment. We note that effective with FY 2022 and forward, CMS is changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We note that the adjustment relies on the same underlying data and methodology. This new terminology is more consistent with the statutory language described in section 1886(b)(3)(B)(xi)(II) of the Act.

b. Calculation of Factor 2 for FY 2022

(1) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. In FY 2020 and subsequent fiscal years, there is no longer a reduction. We note that, unlike section 1886(r)(2)(B)(i) of the Act, which governed the calculation of Factor 2 for FYs 2014, 2015, 2016, and 2017, section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65 years of age.

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197), in our analysis of a potential data source for the rate of uninsurance for purposes of computing Factor 2 in FY 2018, we considered the following: (1) The extent to which the source accounted for the full U.S. population; (2) the extent to which the source comprehensively accounted for both public and private health insurance coverage in deriving its estimates of the number of uninsured; (3) the extent to which the source utilized data from the Census Bureau; (4) the timeliness of the estimates; (5) the continuity of the estimates over time; (6) the accuracy of the estimates; and (7) the availability of projections (including the availability of projections using an established estimation methodology that would allow for calculation of the rate of uninsurance for the applicable Federal fiscal year). As we explained in the FY 2018 IPPS/LTCH PPS final rule, these considerations are consistent with the statutory requirement that this estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and help to ensure the data source will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. We proposed to use a methodology similar to the one that was used in FY 2018 through FY 2021 to determine Factor 2 for FY 2022.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we determined the source that, on balance, best meets all of these considerations is the uninsured estimates produced by OACT as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured, because this information is integral to the well-established NHEA methodology. A full description of the methodology used to develop the NHEA is available on the CMS website at: *https://www.cms.gov/files/document/definitions-sources-and-methods.pdf*.

The NHEA estimates of U.S. population reflect the Census Bureau's definition of the resident-based population, which includes all people who usually reside in the 50 States or the District of Columbia, but excludes residents living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside of the U.S., plus a small (typically less than 0.2 percent of population) adjustment to reflect Census undercounts. For fiscal years 2014 through 2017, the estimates for Factor 2 were made using the CBO's uninsured population estimates for the under 65 population. For FY 2018 and subsequent years, the statute does not restrict the estimate to the measurement of the percent of individuals under the age of 65 who are uninsured. Accordingly, as we explained in the FY 2018 IPPS/LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate

of uninsurance in the U.S. across all age groups. In addition, we continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than an estimate that reflects only legal residents. The NHEA estimates of uninsurance are for the total U.S. population (all ages) and not by specific age cohort, such as the population under the age of 65.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2019, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2019. The NHEA data are publicly available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*.

In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the website at: *http://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at: *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2019, OACT extrapolates from the 2009 CPS data through 2018 using data from the National Health Interview Survey (NHIS) and then, for 2019, OACT extrapolates using the American Community Survey (ACS). The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). For both the NHIS and ACS, the U.S. Census Bureau is the data collection agent. The results from these data sources have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at: *https://www.cdc.gov/nchs/nhis/index.htm*. For further information regarding the ACS, we refer readers to the Census Bureau's website at: *https://www.census.gov/programs-surveys/acs/*. In deriving the number of uninsured for the most recent release of the national health expenditure accounts, there were two concerns related to the data sources typically used. The NHIS underwent a redesign in 2019 and cautioned its users against comparing the year-over-year trend from 2018–2019 as a result. Also, the Census Bureau indicated that it experienced data collection issues for the 2019 CPS, which may have been affected by the COVID–19 pandemic, and similarly cautioned its users to be aware of the potential impact on trend analysis between 2018 and 2019. Consequently, the ACS data were used for estimating 2019.

The next metrics needed to compute Factor 2 are projections of the rate of uninsurance in both CY 2021 and CY 2022. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. Those projections use the latest NHEA historical data, available at the time of their construction. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The sources for projected growth rates in enrollment for Medicare, Medicaid, and CHIP include the latest Medicare Trustees Report, the Medicaid Actuarial Report, or other updated estimates as produced by OACT. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on the set of macroeconomic assumptions underlying the latest Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

The use of data from the NHEA to estimate the rate of uninsurance is consistent with the statute and meets the criteria we have identified for determining the appropriate data source. Section 1886(r)(2)(B)(ii) of the Act instructs the Secretary to estimate the rate of uninsurance for purposes of Factor 2 based on data from the Census Bureau or other sources the Secretary determines appropriate. The NHEA utilizes data from the Census Bureau; the estimates are available in time for the IPPS rulemaking cycle; the estimates are produced by OACT on an annual basis and are expected to continue to be produced for the foreseeable future; and projections are available for calendar year time periods that span the upcoming fiscal year. Timeliness and continuity are important considerations because of our need to be able to update this estimate annually. Accuracy is also a very important consideration and, all things being equal, we would choose the most accurate data source that sufficiently meets our other criteria.

We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for the FY 2022 IPPS/LTCH proposed rule for further details on the methodology and assumptions that were used in the projection of the uninsurance rate.[762]

(2) Factor 2 for FY 2022

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25448 and 25449), using these data sources and the previously described methodologies, OACT estimated that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2021 and 2022 is 10.2 percent and 10.1 percent, respectively. The projected rates of uninsurance for CY 2021 and 2022 reflect the estimated impact of the COVID–19 pandemic. As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates. However, for purposes of this final rule, we note that the OACT has added an addendum to the memo to reflect an updated estimate of projected rates of uninsurance for CY

[762] OACT Memorandum on Certification of Rates of Uninsured. March 12, 2021. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInPatientPPS/dsh.html*.

2021 and 2022, as discussed in our responses to comments.

As with the CBO estimates on which we based Factor 2 for fiscal years before FY 2018, the NHEA estimates are for a calendar year. Under the approach originally adopted in the FY 2014 IPPS/LTCH PPS final rule, we have used a weighted average approach to project the rate of uninsurance for each fiscal year. We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, we proposed to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2022.

As part of the development of the proposed Factor 2 for FY 2021, OACT certified the estimate of the rate of uninsurance for FY 2022 determined using this weighted average approach to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act. However, in the proposed rule, we noted that we might also consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2022. In particular, we noted that any potential impacts from the American Rescue Plan Act were not reflected in our estimates for the proposed rule, due to the timing for the development and publication of the FY 2022 IPPS/LTCH proposed rule.

In the proposed rule, we outlined the calculation of the proposed Factor 2 for FY 2022 as follows:

Percent of individuals without insurance for CY 2013: 14 percent.

Percent of individuals without insurance for CY 2021: 10.2 percent.

Percent of individuals without insurance for CY 2022: 10.1 percent.

Percent of individuals without insurance for FY 2022 (0.25 times 0.0102) + (0.75 times 0.0101): 10.1 percent.

1- |((0.101 − 0.14)/0.14)| = 1 − 0.2786 = 0.7214 (72.14 percent).

For FY 2020 and subsequent fiscal years, section 1886(r)(2)(B)(ii) of the Act no longer includes any reduction to the previous calculation in order to determine Factor 2. Therefore, we proposed that Factor 2 for FY 2022 would be 72.14 percent.

The proposed FY 2022 uncompensated care amount was $10,573,368,841.28 * 0.7214 = $7,627,628,282.10.

Proposed FY 2022 Uncompensated Care Amount	$ 7,627,628,282.10

We invited public comments on the proposed Factor 2 for FY 2022.

Comment: As with the comments received on proposed Factor 1, a majority of commenters discussed the proposed Factor 2 in the context of the COVID–19 PHE. Many commenters urged CMS to be transparent in the calculation of Factor 2 and stated that agency assumptions and data sources should be accurate and publicly available. Many commenters urged OACT to update its projections of the rates of uninsurance to reflect changes in the rate of uninsurance due to the COVID–19 PHE, and in particular, current economic conditions. A commenter also recommended that the agency account for regulatory or legislative changes that could drive up uninsured rates as well as external factors, such as shifts in economic conditions.

Many commenters requested that CMS consider the shifts from commercial insurance to Medicaid when calculating Factor 2. A commenter stated that the writers of the Affordable Care Act could not have foreseen that such a drastic shift in insurance patterns would occur in a short amount of time, as a result of a pandemic.

Many commenters highlighted the proposed decrease of approximately $660 million in total uncompensated care payments in the FY 2022 proposed rule compared to estimated total uncompensated care payments for FY 2021, which, according to a commenter, conflicts with CMS' goal of advancing health equity and reducing healthcare disparities.

Commenters referred to the significant increase in unemployment due to the pandemic and stated that it seems counterintuitive that the percentage of uninsured decreased. Another commenter stated that the reduction in uncompensated care payments, in part because of a projected reduction in the number of uninsured individuals, is inconsistent with the increase in care that hospitals have provided to uninsured patients during the past year. Therefore, many commenters requested that for FY 2022 CMS maintain total uncompensated care payments at the current level for FY 2021, due to the pandemic. Some commenters recommended that CMS follow a similar path as in other IPPS policies proposed for FY 2022 and use FY 2019 data again in place of FY 2020 data when calculating the uninsured rates for Factor 2.

A commenter indicated that other government reports have contradicted many of the most important assumptions made concerning Factor 2. For example, the CBO issued a report on nationwide health insurance levels, which concluded that the Affordable Care Act had insured fewer individuals than previously estimated. Additionally, they noted that in the President's 2018 Economic Report, the Administration noted that not only was the overall coverage expansion less than initially expected, but it was also due more to Medicaid expansion than was initially projected.

A commenter also noted that in projecting coverage levels for FY 2022, the proposed rule assumed an under-reporting of Medicaid coverage ''due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance,'' yet there is nothing in the proposed rule to indicate that the agency has applied this same presumption of under reporting in calculating Factor 1, where increased Medicaid coverage would serve to increase expected DSH payments. The commenter concluded that it appears that the agency has applied internally inconsistent assumptions on Medicaid expansion between Factors 1 and 2 with no explanation.

Many commenters recommended using the latest available data when finalizing Factor 2. Commenters believed that using more timely and accurate data would reflect an increase in the uninsured population in FY 2021 and FY 2022. A commenter requested that CMS revisit its approach to calculating uncompensated care funding, as current data likely includes too much noise.

Response: We thank the commenters for their input and their recommendations regarding the estimate of Factor 2 included in the proposed rule. We refer readers to the Addendum to the OACT memo for further details on the methodology and updated assumptions used in the calculation of

the projection of the uninsurance rate for this final rule. In brief, using the past estimates from NHEA from earlier this year as a baseline, OACT estimated the impacts of employment changes on insurance coverage to update the estimate of the rates of uninsurance for CY 2021 and CY 2022. We note that this approach takes into account relevant developments since publication of the proposed rule, including faster-than-anticipated employment growth, an improving economic outlook based on a consensus of the Blue Chip forecasters, and substantial recent and anticipated, temporary increases in Medicaid enrollment (associated in part with the Maintenance of Effort requirement under the FFCRA for states to qualify to receive higher Medicaid payments during the PHE).

In response to the comments concerning transparency, we reiterate that we have been and continue to be transparent with respect to the methodology and data used to estimate Factor 2. The FY 2022 IPPS/LTCH PPS proposed rule included a detailed discussion of our proposed Factor 2 methodology as well as the data sources that would be used in making our final estimate. For purposes of this final rule, we are using an updated projected rate of uninsurance to better reflect the impact of the PHE for the COVID–19 pandemic. A detailed description of the methodology used to update our estimates can be found in the accompanying memo (available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh*). Section 1886(r)(2)(B)(ii) of the Act permits us to use a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. We continue to believe that the NHEA data and methodology that were used to estimate Factor 2 for this final rule are transparent and best meet all of our considerations for ensuring reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. We also believe it is appropriate to update the NHEA-based projection of the FY 2022 rate of uninsurance that appeared in the proposed rule using recent unemployment data from BLS, and associated projections of that metric as published in the Blue Chip Economic Indicators report.

Many commenters requested that CMS consider the shifts from commercial insurance to Medicaid when calculating Factor 2. The projections utilized here capture shifts between insurance categories such as from commercial insurance to Medicaid and any resulting impact on the uninsured population. Regarding the comments recommending that we maintain total uncompensated care payments at the FY 2021 level, we note that section 1886(r)(2)(B)(ii) provides that Factor 2 should be determined by comparing the percent of individuals who are uninsured in 2013 with the number of individuals ''who are uninsured in the most recent period for which data is available.'' Because data are available to permit OACT to estimate the rate of uninsurance for CY 2021 and CY 2022, we believe using these data to estimate Factor 2 for FY 2022 is appropriate and consistent with the statute. In particular, maintaining total uncompensated care payments at the FY 2021 level would fail to reflect updated expectations regarding the level of uninsurance during FY 2022 associated with changing economic conditions, newly available data on Medicaid and Marketplace enrollment, the estimated impacts from the Families First Coronavirus Response Act (FFCRA), including the provision requiring a Medicaid Maintenance of Effort, the CARES Act, and the American Rescue Plan Act.

After consideration of the public comments we received, we are updating the calculation of Factor 2 for FY 2022 to incorporate more recent data, as we proposed. The final estimates of the percent of uninsured individuals have been certified by the Chief Actuary of CMS. The calculation of the final Factor 2 for FY 2022 using a weighted average of OACT's updated projections for CY 2021 and CY 2022 is as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2021: 9.8 percent.
- Percent of individuals without insurance for CY 2022: 9.5 percent.
- Percent of individuals without insurance for FY 2022 (0.25 times 0.098) + (0.75 times 0.095): 9.6 percent.

1- |((0.096 − 0.14)/0.14)| = 1 − 0.3143 = 0.6857 (68.57 percent). Therefore, the final Factor 2 for FY 2022 is 68.57 percent. The final FY 2022 uncompensated care amount is $10,488,564,546.74 * 0.6857 = $7,192,008,709.70.

FY 2022 Final Rule Uncompensated Care Amount	$ 7,192,008,709.70

c. Calculation of Factor 3 for FY 2022

(1) General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) The amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of

computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year for which section 1886(r) of the Act was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report would potentially provide the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FYs 2015, 2016, or 2017. Instead, we used alternative data on the utilization of insured low-income patients, as measured by patient days, which we believed would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. Of particular importance in our decision to use proxy data was the relative newness of Worksheet S–10, which went into effect on May 1, 2010. At the time of the rulemaking for FY 2014, the most recent available cost reports would have been from FYs 2010 and 2011 and submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. However, we indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. Analyses performed by MedPAC had already shown that the correlation between audited uncompensated care data from 2009 and the data from the FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 between the audited uncompensated care data and 2011 Medicare SSI and Medicaid days. Based on this analysis, MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the data reported on Worksheet S–10 would improve over time as the data are actually used to make payments (81 FR 25090). In addition, a 2007 MedPAC analysis of data from the Government Accountability Office (GAO) and the American Hospital Association (AHA) had suggested that Medicaid days and low-income Medicare days are not an accurate proxy for uncompensated care costs (80 FR 49525).

Subsequent analyses from Dobson/DaVanzo, originally commissioned by CMS for the FY 2014 rulemaking and updated in later years, compared Worksheet S–10 and IRS Form 990 data and assessed the correlation in Factor 3s derived from each of the data sources. Our analyses on balance led us to believe that we had reached a tipping point in FY 2018 with respect to the use of the Worksheet S–10 data. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38203) for a complete discussion of these analyses. We found further evidence for this tipping point when we examined changes to the FY 2014 Worksheet S–10 data submitted by hospitals following the publication of the FY 2017 IPPS/LTCH PPS final rule.

We also recognized commenters' concerns that, in continuing to use Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. Because the earliest Medicaid expansions under the Affordable Care Act began in 2014, the 2011, 2012, and 2013 Medicaid days used to calculate uncompensated care payments in FYs 2015, 2016, and 2017 are the latest available data on Medicaid utilization that do not reflect the effects of these Medicaid expansions. Accordingly, if we had used only low-income insured days to estimate uncompensated care for FY 2018, we would have needed to hold the time period of these data constant and use data on Medicaid days from 2011, 2012, and 2013 in order to avoid the risk of any redistributive effects arising from the decision to expand Medicaid in certain States. In the FY 2018 IPPS/LTCH PPS final rule, we finalized a methodology under which we calculated Factor 3 for all eligible hospitals, with the exception of Puerto Rico hospitals and Indian Health Service (IHS) and Tribal hospitals, using Worksheet S–10 data from FY 2014 cost reports in conjunction with low-income insured days proxy data based on Medicaid days and SSI days. The time period for the Medicaid days data was FY 2012 and FY 2013 cost reports (82 FR 38208 through 38213).

As we stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41414), with the additional steps we had taken to ensure the accuracy and consistency of the data reported on Worksheet S–10 since the publication of the FY 2018 IPPS/LTCH PPS final rule, we continued to believe that we could no longer conclude that alternative data to the Worksheet S–10 are currently available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Similarly, the actions that we have taken to improve the accuracy and consistency of the Worksheet S–10 data, including the opportunity for hospitals to resubmit Worksheet S–10 data for FY 2015, led us to conclude that there were no alternative data to the Worksheet S–10 data currently available for FY 2015 that would be a better proxy for the costs of subsection (d) hospitals for treating uninsured individuals. Accordingly, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41428), we advanced the time period of the data used in the calculation of Factor 3 forward by 1 year and used Worksheet S–10 data from FY 2014 and FY 2015 cost reports in combination with the low income insured days proxy for FY 2013 to determine Factor 3 for FY 2019. We note that, as discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42366), the use of three years of data to determine Factor 3 for FY 2018 and FY 2019 had the effect of smoothing the transition from the use of low-income insured days to the use of Worksheet S–10 data.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41424), we received overwhelming feedback from commenters emphasizing the

importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10. We began auditing the Worksheet S–10 data for selected hospitals in the Fall of 2018 so that the audited uncompensated care data from these hospitals would be available in time for use in the FY 2020 IPPS/LTCH PPS proposed rule. The audits began with 1 year of data (that is, FY 2015 cost reports) in order to maximize the available audit resources and not spread those audit resources over multiple years, potentially diluting their effectiveness. We chose to begin the audits with the FY 2015 cost reports primarily because this was the most recent year of data that we had broadly allowed to be resubmitted by hospitals, and many hospitals had already made considerable efforts to amend their FY 2015 reports in preparation for the FY 2019 rulemaking. We also considered that we had used the FY 2015 data as part of the calculation of the FY 2019 uncompensated care payments; therefore, the data had been subject to public comment and scrutiny.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42368), we finalized our proposal to use a single year of Worksheet S–10 cost report data from FY 2015 in the methodology for determining Factor 3 for FY 2020. Although some commenters expressed support for the alternative policy of using the FY 2017 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2020, given the feedback from commenters in response to both the FY 2019 and FY 2020 IPPS/LTCH PPS proposed rules, emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we concluded that the FY 2015 Worksheet S–10 data were the best available audited data to be used in determining Factor 3 for FY 2020. We also noted that we had begun auditing the FY 2017 data in July 2019, with the goal of having the FY 2017 audited data available for future rulemaking.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58823 through 58825), we finalized our proposal to use the most recent available single year of audited Worksheet S–10 data to determine Factor 3 for FY 2021 and subsequent fiscal years. We explained our belief that using the most recent audited data available before the applicable Federal fiscal year, will more accurately reflect a hospital's uncompensated care costs, as opposed to averaging multiple years of data. We noted that if a hospital has relatively different data between cost report years, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3. Therefore, we also believed using a single year of audited cost report data is an appropriate methodology to determine Factor 3 for FY 2021 and subsequent years, except for IHS and Tribal hospitals and hospitals located in Puerto Rico. For IHS and Tribal hospitals and Puerto Rico hospitals, we finalized the use of a low-income insured days proxy to determine Factor 3 for FY 2021. We did not finalize a methodology to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals for FY 2022 and subsequent years because we believed further consideration and review of these hospitals' Worksheet S–10 data was necessary (85 FR 58825).

In the FY 2021 IPPS/LTCH PPS final rule, we finalized the definition ''uncompensated care'' for FY 2021 and subsequent fiscal years, for purposes of determining uncompensated care costs and calculating Factor 3 (85 FR 58825 through 58828). We are continuing to use the definition that we had initially adopted in the FY 2018 IPPS/LTCH PPS final rule. Specifically, ''uncompensated care'' is defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). We refer readers to the FY 2021 IPPS/LTCH PPS rule (85 FR 58825 through 58828) for a discussion of additional topics related to the definition of uncompensated care. We noted in the FY 2021 IPPS/LTCH PPS final rule that the Paper Reduction Act (PRA) package for Form CMS–2552–10 (OMB Control Number 0938–0050, expiration date March 31, 2022) would offer an additional opportunity to comment on the cost reporting instructions. A PRA package with comment period appeared in the November 10, 2020 **Federal Register** (85 FR 71653). We thank stakeholders for their comments on the PRA package and we will respond to those comments in a separate **Federal Register** document.

(2) Background on the Methodology Used To Calculate Factor 3 for FY 2021 and Subsequent Fiscal Years

Section 1886(r)(2)(C) of the Act governs both the selection of the data to be used in calculating Factor 3, and also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for a subsection (d) hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2021 IPPS/LTCH PPS final rule, we applied the following policies as part of the Factor 3 methodology: (1) The policy regarding newly merged hospitals that was initially adopted in the FY 2015 IPPS/LTCH PPS final rule; (2) the policies regarding annualization and long cost reports that were adopted in the FY 2018 and FY 2019 IPPS/LTCH PPS final rules, including a modified policy for the rare cases where a provider has no cost report for the fiscal year that is used in the Factor 3 methodology because the cost report for the previous fiscal year spans both years; (4) the modified new hospital policy that was finalized in the FY 2020 IPPS/LTCH PPS final rule; (5) the new merger policy adopted in the FY 2021 IPPS/LTCH PPS final rule that accounts for the merger effective date; and (6) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58829), we continued to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care

burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year would be recalculated similar to new hospitals (79 FR 50021 and 50022). Consistent with past policy, interim uncompensated care payments for newly merged hospitals are based only on the data for the surviving hospital's CCN available the time of the development of the final rule. However, at cost report settlement, we will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2021 cost report. That is, we will revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2021 cost report.

In FY 2021 IPPS/LTCH PPS final rule (85 FR 58829), we continued the policy that was finalized in the FY 2018 IPPS/LTCH PPS final rule of annualizing uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data, except in the case of mergers, which would be subject to the modified merger policy adopted for FY 2021. In addition, we continued the policies that were finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41415) regarding the use of the longest cost report available within the Federal fiscal year. However, we adopted a modified policy for those rare situations where a hospital has a cost report that starts in one fiscal year but spans the entirety of the following fiscal year such that the hospital has no cost report starting in that subsequent fiscal year. Under this modified policy, we use the cost report that spans both fiscal years for purposes of calculating Factor 3 when data from the latter fiscal year are used in the Factor 3 methodology.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58829 and 58830), we continued the modified new hospital policy for new hospitals that did not have data for the cost reporting period(s) used in the Factor 3 calculation for FY 2021. Under the modified policy originally adopted for FY 2020, new hospitals that have a preliminary projection of being eligible for Medicare DSH based on their most recent available disproportionate patient percentages may receive interim empirically justified DSH payments. However, because these hospitals did not have a FY 2017 cost report to use in the Factor 3 calculation and the projection of eligibility for DSH payments was still preliminary, the MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2021 cost report. If the hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2021, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2021 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2017 cost reports for all DSH-eligible hospitals.

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a new merger policy that accounts for the merger effective date (85 FR 58828 through 58829). To more accurately estimate UCC for the hospitals involved in a merger when the merger effective date occurs partway through the surviving hospital's cost reporting period, we finalized a policy of not annualizing the acquired hospital's data. Under this policy, we use only the portion of the acquired hospital's unannualized UCC data that reflects the UCC incurred prior to the merger effective date, but after the start of the surviving hospital's current cost reporting period. To do this, we calculate a multiplier to be applied to the acquired hospital's UCC. This multiplier represents the portion of the UCC data from the acquired hospital that should be incorporated with the surviving hospital's data to determine UCC for purposes of determining Factor 3 for the surviving hospital. This multiplier is obtained by calculating the number of days between the start of the applicable cost reporting period for the surviving hospital and the merger effective date, and then dividing this result by the total number of days in the reporting period of the acquired hospital. Applying this multiplier to the acquired hospital's unannualized UCC data will determine the final portion of the acquired hospital's UCC that should be added to that of the surviving hospital for purposes of determining Factor 3 for the merged hospital.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831 and 58832), we continued to apply a CCR trim methodology similar to the CCR trim methodology policy that has been used for purposes of determining uncompensated care payments since FY 2018. This CCR trim methodology is consistent with the approach used in the outlier payment methodology under § 412.84(h)(3)(ii), which states that the Medicare contractor may use a statewide average CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean. We refer readers to the discussion in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831) for a detailed description of the steps used to determine the applicable CCR.

In addition, we continued the UCC data trim methodology for rare situations where a hospital has potentially aberrant data that are unrelated to its CCR (85 FR 58832). However, because we had audited the FY 2017 Worksheet S–10 data for a number of hospitals, we explained that we no longer believe it is necessary to apply the trim methodology for hospitals whose cost report has been audited. Accordingly, for FY 2021 we finalized a policy under which we exclude hospitals that were part of the audits from the trim methodology for potentially aberrant UCC. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831), we also modified the potentially aberrant UCC trim methodology when it is applied to all-inclusive rate providers (AIRPs). Under this modified trim methodology, when an AIRP's total UCC are greater than 50 percent of its total operating costs when calculated using the CCR included on its FY 2017 cost report, we will recalculate the AIRP's UCC using the CCR reported on Worksheet S–10, line 1 of the hospital's most recent available prior year cost report that does not result in UCC of over 50 percent of total operating costs.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58824 and 58825), we continued the policy we first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3 for IHS and Tribal hospitals and subsection (d) Puerto Rico hospitals that have a FY 2013 cost report. We stated our belief that this approach was appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In addition, because we continued to use 1 year of insured low income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58817) for a discussion of the approach that we continued in FY 2021 to determine Factor 3 for new Puerto Rico hospitals. In brief, Puerto Rico hospitals that do not have a FY 2013 cost report are considered new hospitals and subject to the new hospital policy, as discussed previously. Specifically, the numerator of the Factor 3 calculation will be the uncompensated care costs reported on Worksheet S–10 of the hospital's cost report for the applicable fiscal year and the denominator is the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals.

Therefore, for FY 2021, we finalized the following methodology to compute Factor 3 for each hospital:

Step 1: Selecting the provider's longest cost report from its Federal fiscal year (FFY) 2017 cost reports. (Alternatively, in the rare case when the provider has no FFY 2017 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2017 time period, the previous Federal fiscal year cost report would be used in this step.)

Step 2: Annualizing the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combining adjusted and/or annualized uncompensated care costs for hospitals that merged.

Step 4: Calculating Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals that have a FY 2013 cost report using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). (Alternatively, in the rare case when a provider has no FFY applicable cost report because the cost report for the previous Federal fiscal year spanned the time period, the previous Federal fiscal year cost report would be used in this step.) The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals. Consistent with the policy adopted in the FY 2019 IPPS/LTCH PPS final rule, if a hospital did not have both Medicaid days for FY 2013 and SSI days for FY 2018 available for use in the calculation of Factor 3 in Step 4, we considered the hospital not to have data available for Step 4.

Step 5: Calculating Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2017 cost report data (from Step 1, 2, or 3). The hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We also stated that the methodology adopted in the FY 2021 IPPS/LTCH PPS final rule for purposes of determining Factor 3 for FY 2021 would apply for FY 2022 and subsequent years, using Worksheet S–10 data from the most recent cost reporting year for which audits have been conducted. However, we did not finalize a methodology to determine Factor 3 for FY 2022 and subsequent years for IHS and Tribal hospitals and Puerto Rico hospitals that have a FY 2013 cost report because we believed further consideration and review of these hospitals' Worksheet S–10 data is necessary.

We amended the regulations at § 412.106(g)(1)(iii)(C) by adding a new paragraph (7) to reflect the methodology for computing Factor 3 for FY 2021. We also added a new paragraph (8) to reflect the policy adopted for all subsequent fiscal years of using the most recent available single year of audited Worksheet S–10 data to calculate Factor 3 for all eligible hospitals, except IHS and Tribal hospitals and Puerto Rico Hospitals.

(3) Methodology for Calculating Factor 3 for FY 2022

(a) Use of Audited FY 2018 Data To Calculate Factor 3 for FY 2022

Audits of FY 2018 cost reports began in 2020 and those audited reports were available, in time for the development of the proposed rule. Feedback from the audits of the FY 2015 and FY 2017 reports and lessons learned were incorporated into the audit process for the FY 2018 reports. We again chose to audit 1 year of data (that is, FY 2018) in order to maximize the available audit resources and not spread those audit resources over multiple years, potentially diluting their effectiveness.

Given that the FY 2018 Worksheet S–10 data are the most recent available audited data, in the FY 2022 IPPS/LTCH PPS proposed rule, we stated that we believe, on balance, that the FY 2018 Worksheet S–10 data are the best available data to use for calculating Factor 3 for FY 2022. As discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules (84 FR 19419 and 84 FR 42364), we continue to believe that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result. To the extent that the audited FY 2018 data for a hospital may be relatively different from its FY 2017 data (whether audited or unaudited), we potentially would be diluting the effect of the revisions to the cost reporting instructions and our considerable auditing efforts, while introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3 for FY 2022. In the FY 2022 IPPS/LTCH proposed rule, we recognized that the FY 2017 reports also include audited data for some hospitals. However, the FY 2018 cost reports are the most recent year of audited data and, and reflect the revisions to the Worksheet S–10 cost report instructions that were effective on October 1, 2017.

Accordingly, consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule and codified in the regulations at § 412.106(g)(8), in the FY 2022 IPPS/LTCH PPS proposed rule we used a single year of Worksheet S–10 data from FY 2018 cost reports to calculate Factor 3 for FY 2022 for all eligible hospitals with the exception of IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013. As discussed in a later section, we proposed to continue to use the low-income insured days proxy to calculate Factor 3 for these hospitals for one more year. In the proposed rule, we noted that the proposed uncompensated care payments to hospitals whose FY 2018 Worksheet S–10 data have been audited represent approximately 99.6 percent of the proposed total uncompensated care payments for FY 2022. For purposes of the FY 2022 IPPS/LTCH PPS proposed rule, we used a HCRIS extract updated through February 19, 2021. We also noted that we intended to use the March 2021 update of HCRIS for the FY 2022 final rule and the respective March updates for all future final rules. However, we also indicated that we might consider the use of more recent data that may become available after March 2021, but prior to the development of the final rule, if appropriate, for purposes of calculating the final Factor 3 for the FY 2022 IPPS/LTCH PPS final rule. We invited public comments on our proposed methodology for calculating Factor 3 for FY 2022, including, but not limited to, our proposed use of FY 2018 Worksheet S–10 data (86 FR 25457).

Comment: Several commenters expressed general support for the use of audited Worksheet S–10 data to estimate each hospital's share of uncompensated care costs in FY 2022 and/or in future years. Commenters commended CMS for its efforts to

ensure the accuracy and consistency of the data reported through revised instructions and ongoing refinements to the audit process.

A commenter expressed concerns about the validity and comparability of Worksheet S–10 data, especially in the absence of auditing all DSH-eligible hospitals. Another commenter asserted that using Worksheet S–10 data to calculate Factor 3 could result in an inequitable distribution because Worksheet S–10 does not ''offset hospital UC [uncompensated care] losses with non-Medicare sources of subsidies such as Medicaid DSH and related Medicaid waiver [uncompensated care] pool funds.'' A commenter recommended that CMS eliminate the reliance on Worksheet S–10 data as a measure of uncompensated care because Worksheet S–10 methodology does not account for hospitals with high levels of uncompensated care from patients on public insurance. The commenter noted that these hospitals with high uncompensated care are unable to offset their charity care and bad debt losses with additional sources such as direct taxes or state and local appropriations. They recommended that CMS develop a measure that acknowledges those inherent problems or make exceptions and provide specific protections for hospitals that serve very low-income and medically complex populations. Another commenter requested that CMS ensure its methodology for determining UC payments accurately captures the full range of UC costs that hospitals incur when treating low-income and uninsured individuals to ensure safety net hospitals receive adequate support.

Response: We appreciate the support for our policy of using the most recent year of audited Worksheet S–10 data for the computation of Factor 3. We also appreciate the input from those commenters who are opposed to the use of data from Worksheet S–10 in the calculation of Factor 3. Regarding those comments that expressed concerns that Worksheet S–10 data lack validity and are not comparable across hospitals, we note that consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule, we are continuing to use audited Worksheet S–10 cost report data to determine Factor 3 for FY 2022. Our decision to adopt a policy of using audited Worksheet S–10 data to determine Factor 3 was based upon the results of analyses of Worksheet S–10 data conducted both internally and by stakeholders which demonstrate that Worksheet S–10 accuracy has improved over time. As part of our ongoing quality control and data improvement measures, we have revised the cost report instructions (Transmittal 11). Additionally, we have conducted audits of the FY 2018 Worksheet S–10 data for an expanded number of hospitals, and we have begun auditing the FY 2019 Worksheet S–10 data to further improve provider reporting and overall accuracy. Moreover, as hospitals gain more experience with completing the Worksheet S–10 and build upon lessons learned from the audits, we believe the data obtained from these cost reports will continue to improve and become more consistent. Therefore, we continue to believe that the Worksheet S–10 data is the best available source for the uncompensated care costs of subsection (d) hospitals.

Comment: Many commenters supported the use of a single year of FY 2018 Worksheet S–10 data for the calculation of Factor 3 for FY 2022. Commenters noted that the FY 2018 cost reports are the most recent reports which have been subject to audit and that these audits have continued to improve the accuracy and reliability of Worksheet S–10 data over time. Commenters supporting the continued use of Worksheet S–10 data also indicated that the FY 2018 cost reports are the most extensive as significantly more hospitals underwent Worksheet S–10 audits. In addition, some commenters indicated that the FY 2018 cost reports reflect the improvements called for under the most recent revised Worksheet S–10 instructions.

However, many other commenters expressed opposition to using a single year of Worksheet S–10 data in the calculation of uncompensated care payments for FY 2022 and future years. The primary concern expressed by these commenters was the possibility that such an approach would lead to significant variation in year-to-year uncompensated care payments, especially in light of external factors that may affect a hospital's finances on a one-time basis. These commenters pointed to CMS' historical practice of using data from multiple years to determine uncompensated care payments and argued that such an approach would mitigate year-to-year fluctuations and avoid a skewed distribution of uncompensated care payments, while also ensuring accuracy, stability, and predictability for providers. Some stakeholders indicated that CMS will no longer have to be concerned about mixing audited and unaudited data from multiple years as the agency continues to audit Worksheet S–10 data each year.

The most common alternative recommended by commenters who opposed the use of a single year of FY 2018 data for the calculation of Factor 3 in FY 2022 was the use of two years of historical Worksheet S–10 data. Several commenters recommended a transitional period where FY 2017 and FY 2018 Worksheet S–10 data would be used to determine Factor 3 for FY 2022, because both years have been subject to audits. These commenters also suggested the use of FY 2017, FY 2018, and FY 2019 data to determine FY 2023 uncompensated care payments, followed by the continued use of three years of audited Worksheet S–10 data thereafter. As an alternative, a commenter suggested the use of audited FY 2018 and FY 2019 data to determine Factor 3 for FY 2023, and a subsequent transition to using three years of audited data for the FY 2024 uncompensated care payments, if using data from more than one year's cost report for FY 2022 was not feasible.

Some commenters acknowledged the efforts CMS has taken to improve the accuracy of Worksheet S–10 data through the audit process. Yet, several commenters expressed concerns about the accuracy and reliability of using a single year of Worksheet S–10 audited data. Some commenters requested that CMS further monitor uncompensated care payments over time for potential anomalies and fluctuations. Other commenters recommended CMS consider omitting or making appropriate adjustments to cost report data due to the effects of the COVID–19 public health emergency (PHE) when calculating Factor 3 and determining the distribution of uncompensated care payments in future years. In addition, a commenter suggested that CMS regularly assess the cost report data for irregular trends and their potential impact on the allocation of uncompensated care payments.

Response: We are grateful to those commenters who expressed their support for using the FY 2018 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2022. As noted in the FY 2022 IPPS/LTCH PPS proposed rule, we believe, that, on balance, the FY 2018 Worksheet S–10 data are the best available data to use for calculating Factor 3 for FY 2022.

Regarding the commenters' suggestion of using multiple years of audited Worksheet S–10 data, we will consider using multiple years of data when the vast majority of providers have been audited for more than one fiscal year under the revised reporting instructions. We expect that the number of audits will continue to increase from previous years. Further, we continue to believe

that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result. To the extent that the audited FY 2018 Worksheet S–10 data for a hospital are relatively different from its audited or unaudited FY 2017 Worksheet S–10 data (for example, as a general statement, audits can materially impact a hospital's data), we potentially would be diluting the effect of the revisions to the cost reporting instructions and our considerable auditing efforts, while introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3 for FY 2022. For example, there are some unaudited FY 2017 reports that have a larger than $5 million absolute difference in uncompensated care costs between a hospital's unaudited FY 2017 report and a hospital's audited FY 2018 report. We believe using the most recent year of audited data is an appropriate methodology for DSH uncompensated care payments.

As explained in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58820), we also note that if a blend of multiple years of cost report data (for example, FY 2017, FY 2018, and/or FY 2019) were to be used, some hospitals in states that expanded Medicaid eligibility during this time period may have experienced significant reductions in uncompensated care costs following the expansion due to increased Medicaid coverage of many previously uninsured individuals. In this situation, if an average that included pre-expansion uncompensated care cost data were used, the Factor 3 calculated for the hospital may be a less accurate reflection of the relative uncompensated care burden of the hospital. Thus, we believe using only the FY 2018 cost report data will result in a more accurate and more updated reflection of each hospital's proportion of uncompensated care costs. We also agree with those commenters that noted FY 2018 cost reports reflect the first year of data reported under the revised to Worksheet S–10 instructions that were effective on October 1, 2017, and have further improved the data quality. Accordingly, consistent with the regulation at § 412.106(g)(1)(iii)(C)(8), we will calculate Factor 3 for FY 2022 using FY 2018 Worksheet S–10 data, which is the most recent cost reporting year for which audits have been conducted and which we continue to believe is the best available data for purposes of calculating Factor 3 for FY 2022.

For the same reasons, we also continue to have confidence that the best available data in future years will be the Worksheet S–10 data for cost reporting years for which audits have been conducted under the revised reporting instructions. Regarding the commenters' suggestions for FY 2023 and FY 2024, we are not making any modifications to our existing policy on calculating Factor 3 for future fiscal years at this time. We will continue to monitor uncompensated care payments for fluctuations and evaluate any anomalies as we move forward with using only one year of audited Worksheet S–10 data for Factor 3 calculations.

Regarding commenters' concerns about and suggestions for addressing the impact of the COVID–19 PHE in future years, we believe it would be premature to attempt in this rulemaking to modify the methodology for calculating Factor 3 or determining uncompensated care payments for a future fiscal year. We will consider this issue further in future rulemaking when the FY 2020 and FY 2021 cost reporting data are more fully available to be analyzed.

The following comments relate to the definition of uncompensated care costs:

Comment: With regard to the definition of uncompensated care, several commenters urged CMS to include unreimbursed costs (shortfalls) from Medicaid, CHIP, and State and local indigent care programs. According to commenters, these shortfalls represent substantial losses as those programs often do not fully cover the cost of providing care. Several commenters also argued that including Medicaid shortfalls as uncompensated care in Worksheet S–10 is especially important for hospitals in states that have expanded Medicaid. According to the commenters, these hospitals tend to be worse off under the current definition of uncompensated care, as compared to hospitals in states that did not expand. Some commenters provided CMS with methodologies for how to account for Medicaid shortfalls, including a recommendation that CMS develop a measure similar in nature to the Medicaid low-income utilization rate (LIUR) formula that includes Medicaid shortfalls and uninsured care rates to calculate uncompensated care costs for purposes of Factor 3. Another commenter suggested specific revisions to Worksheet S–10 to better reflect the actual Medicaid shortfalls incurred by hospitals. These revisions included allowing hospitals to include all GME-related costs and to reduce their Medicaid revenue by the amount of any contributions to funding the nonfederal share of the Medicaid program, whether through provider taxes, intergovernmental transfers (IGTs), or certified public expenditures (CPEs).

Response: We appreciate commenters' suggestions for revisions and/or modifications to Worksheet S–10. We will consider the concerns raised by commenters as part of future cost report clarifications, and will make modifications as necessary to further improve and refine the information that is reported on Worksheet S–10 to support collection of the information necessary to implement section 1886(r)(2) of the Act. With regard to the comments requesting that payment shortfalls from Medicaid and state and local indigent care programs be included in uncompensated care cost calculations, we continue to believe there are compelling arguments for excluding such shortfalls from the definition of uncompensated care. First, we note that we did not propose any changes to the definition of uncompensated care costs, which was finalized in the FY 2021 IPPS/LTCH PPS final rule as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). Additionally, and as noted in past rulemaking, several key stakeholders, including MedPAC, do not consider Medicaid shortfalls in their definition of uncompensated care. Furthermore, we continue to believe that it is most consistent with section 1886(r)(2) of the Act for Medicare uncompensated care payments to target hospitals that incur a disproportionate share of uncompensated care for patients with no insurance coverage. We also note that even if we agreed that it would be appropriate to adjust the definition of uncompensated care to include Medicaid shortfalls, this would not be a feasible option at this time due to computational limitations. Specifically, computing such shortfalls is operationally problematic because Medicaid pays hospitals a single DSH payment that in part covers the hospital's costs in providing care to the uninsured and in part covers estimates of the Medicaid ''shortfalls.'' Therefore, it is not clear how CMS would determine how much of the ''shortfall'' is left after the Medicaid DSH payment is made. In addition, in some States, hospitals return a portion of their Medicaid revenues to the State via provider taxes and receive supplemental payments in return (along with the Federal match), making the computation of ''shortfalls'' even more complex.

Comment: Commenters also suggested that CMS include all patient care costs when calculating the cost to charge ratio (CCR) used in Worksheet S–10, including costs associated with training medical residents, supporting physician and professional services, and paying provider taxes, so as to determine uncompensated care costs more accurately for purposes of the Worksheet S–10. A commenter also suggested that CMS incorporate the costs of organ transplant programs into the CCR calculation as hospitals incur significant costs related to uninsured and underinsured populations that are not addressed through payments for organ acquisition costs.

Response: As we have consistently stated in past final rules (84 FR 42378 and 85 FR 58826) in response to similar comments, we believe that the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for other costs incurred, including costs associated with supporting and training physicians and other professionals or paying provider taxes associated with Medicaid, as commenters have suggested.

Additionally, because the CCR on Line 1 of Worksheet S–10 is obtained from Worksheet C, Part I, and is also used in other IPPS rate setting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude the costs associated with organ transplant programs, supporting physician and professional services and GME, we remain hesitant to adjust CCRs in the narrower context of calculating uncompensated care costs. Therefore, as stated in past final rules, we continue to believe that it is not appropriate, at this time, to modify the calculation of the CCR on Line 1 of Worksheet S–10 to include any additional costs in the numerator of the CCR calculation.

For issues related to the cost report instruction, which are beyond the scope of this rulemaking, we refer commenters to the forthcoming Paper Reduction Act (PRA) package comment period for Form 2552–10 (OMB Control Number 0938–0050), which will be the appropriate forum for recommending modifications to Worksheet S–10.

Comment: Some stakeholders offered suggestions regarding the uncompensated care payment calculation that appear to be outside the scope of the policies discussed in the proposed rule. One such comment included a recommendation that CMS change the distribution of uncompensated care payments and set a cap on uncompensated care payments, for instance, by implementing a statistical trim threshold on uncompensated care costs reported on the Worksheet S–10 costs that are greater than 40% of Worksheet A expenses. These commenters also suggested that uncompensated care payments in excess of the cap could be redistributed to all other eligible hospitals. Another commenter suggested that hospitals that report aberrant uncompensated care costs on their Worksheet S–10 be penalized by receiving a Factor 3 of 0, rather than a Factor 3 determined using our trim methodology.

In addition, some commenters requested that CMS consider policies to mitigate the effect of the COVID–19 PHE on FY 2020 and FY 2021 cost reports, which will impact future uncompensated care distributions for FY 2024 and FY 2025. In relation to this recommendation, several commenters suggested that CMS consider and/or finalize a policy that would preclude using FY 2020 and FY 2021 Worksheet S–10 data to calculate Factor 3, as these data will likely be affected by COVID–19 PHE and are likely to be unrepresentative of other years, given the unique pressures that hospitals faced during that time.

Response: We thank commenters for their continued concern regarding the distribution of uncompensated care payments and the impact of the COVID–19 PHE on future uncompensated care payments distributions. Regarding commenters' recommendation that we implement a cap on uncompensated care payments, we believe that our policy for trimming uncompensated care costs that are an extremely high ratio, greater than 50 percent, of a hospital's total operating costs for the same year as described the FY 2021 final rule (85 FR 58832), balances our desire to exclude potentially aberrant data with our concern regarding inappropriately reducing uncompensated care payments to a hospital that may have a legitimately high ratio as determined through an audit of their Worksheet S–10 data. Additionally, we note that the statutory language governing Factor 3 does not specify any upper limit to a hospital's uncompensated care payment.

Regarding the commenter's suggestion that hospitals with aberrant cost report data get penalized with a Factor 3 of 0, we note that consistent with the policies adopted in the FY 2021 IPPS/LTCH final rule we intend to continue our policy of trimming potentially aberrant CCRs by applying the state-wide average CCR for providers with a CCR above the proposed ceiling. As discussed previously, we will also continue to implement the trim methodology for potentially aberrant UCC for purposes of determining Factor 3. In addition, for FY 2022, we proposed to trim potentially aberrant charity care cost data for hospitals that are currently not projected to be DSH eligible and do not have audited FY 2018 Worksheet S–10 data by excluding the hospital from the prospective Factor 3 calculation if that hospital's insured patient's charity care costs exceed a threshold of 60 percent of total uncompensated care costs and a dollar threshold of $7 million. We believe these policies appropriately address potentially aberrant data in UCC distribution for the purposes of calculating Factor 3.

The commenters' suggestion that we adjust the methodology for determining uncompensated care costs in this rulemaking to reflect the impact of the COVID–19 PHE is premature. Moreover, it is not clear at this time what methodology would be used to determine any such an adjustment and what data source could be used. Because cost reporting data for the period covered by the COVID–19 PHE is not yet available to be analyzed, we believe it would be premature to attempt in this rulemaking to modify the methodology for determining uncompensated care payments for a future year specifically to address the impact of the COVID–19 PHE. We intend to consider the potential impact of the COVID–19 PHE on the determination of uncompensated care costs in future rulemaking, as appropriate.

The following comments relate to the Worksheet S–10 audit process:

Comment: As in previous years, the auditing process for the FY 2018 Worksheet S–10 was a common topic among many commenters. Several commenters agreed that the data from audited FY 2018 Worksheet S–10s have improved in accuracy when compared to previous years of data and cover a larger share of DSH-eligible hospitals. Other commenters also commended CMS' efforts to improve the Worksheet S–10 data through the audit process and revised instructions. Some commenters agreed that the use of audited Worksheet S–10 data is the most appropriate for calculating Factor 3 and determining DSH payments. A commenter supported CMS' approach of focusing its limited audit resources on the hospitals receiving the highest amounts of uncompensated care payments.

Still, many commenters expressed concerns with the Worksheet S–10 audits. Several commenters

recommended that CMS implement a comprehensive audit process and expand the Worksheet S–10 audits to include all DSH-eligible hospitals receiving uncompensated care payments. In contrast, a commenter recommended that CMS audit a reasonable fraction of providers each year, such as one-third of DSH hospitals, and implement a three year rotation to audit all DSH hospitals over the course of three rulemaking cycles.

Some commenters requested that CMS decrease the provider burden associated with Worksheet S–10 audits, such as by minimizing the significant investment of time and resources required to prepare the necessary audit documentation for auditors. Stakeholders also urged CMS to conduct consistent and equitable audits across providers. Others suggested that CMS revisit the scope of the audits to target specific data elements, which would decrease provider burden.

Additionally, a few commenters suggested that CMS ensure transparency and consistency in the audit process by making the audit materials and protocols publicly available. A commenter also requested that CMS promulgate the audit policy and protocols through notice and comment rulemaking. Some commenters suggested that the Medicare Wage Index audit process could be a model for Worksheet S–10 audits. A commenter referred to the IRS Form 990 audits as separate example. This commenter asserted that the IRS Form 990 audits have been completely different from the Worksheet S–10 audits of uncompensated costs, and stated that the hospitals' IRS audits have not resulted in disallowance.

Other commenters urged CMS to develop a transparent timeframe for the audit process, with communication to providers about expectations and adequate lead time to avoid short response times. A commenter urged CMS to complete audits well in advance of future rulemaking to ensure that cost report data are accurate and available to be used in determining Factor 3. They also requested that CMS establish a standardized and streamlined process across auditors, which would include clear timelines for information submission and guidance on acceptable documentation to meet audit requirements. A commenter also requested that CMS select hospitals for audits in an equitable way and disclose the criteria used to identify hospitals subject to audits.

Commenters noted the need for a timely review and appeals process for any adverse findings or inconsistent audit disallowances. Additionally, commenters urged CMS to consider seeking input from hospitals and working with MACs in developing the Worksheet S–10 audit process to further promote clarity and consistency. To this end, a commenter requested that CMS review audit findings to ensure MACs and their subcontractors are applying audit protocols consistently across hospitals nationwide. A commenter urged CMS to implement fatal edits to ensure that the Worksheet S–10 is submitted completely and is internally consistent, and to instruct MACs to audit negative, missing, or suspicious information.

As part of requesting stability in the Worksheet S–10 audit process, a commenter expressed their concerns with the inconsistent and different sampling and extrapolation techniques employed by MACs during Worksheet S–10 audits. They highlighted the different sampling methods and error rate thresholds used to justify extrapolation, which the commenter believes have produced varied outcomes for hospitals and could impact uncompensated care payments. In addition, this commenter requested that CMS apply the same audit criteria that are used for retrospective audits of empirically justified DSH payments, which are determined using SSI/Medicare and Medicaid eligible days. The commenter also stated that hospitals should have the same protections afforded by the appeal rights available for empirically justified DSH payments.

Response: We thank commenters for their feedback on the audits of the FY 2018 Worksheet S–10 data and their recommendations for future audits. As we have stated previously in response to comments regarding audit protocols, these are provided to the MACs in advance of the audit, in order to assure consistency during the audit process. We began auditing the FY 2018 Worksheet S–10 data for selected hospitals last year so that the audited uncompensated care data for these hospitals would be available in time for use in the FY 2022 IPPS/LTCH PPS proposed rule. We chose to focus the audit on the FY 2018 cost reports in order to maximize the available audit resources. We also note that FY 2018 data are the most recent year of audited data reported under the revised cost report instructions that were effective on October 1, 2017.

In response to the consistent feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we have also started the process of auditing FY 2019 Worksheet S–10 data. We recognize that a number of commenters have suggested we audit all hospitals. However, as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25453), we note that the proposed uncompensated care payments to hospitals whose FY 2018 Worksheet S–10 data have been audited represent approximately 99.6 percent of the proposed total uncompensated care payments for FY 2022, which is an increase from the 65 percent captured in the FY 2017 audits. While our limited audit resources mean that it is not feasible to commit to auditing all hospitals every year, we will continue to expand the number of audited providers captured in the FY 2019 audits, as was done in the FY 2018 audits. We expect the number of audits will continue to increase over time, resulting in improved Worksheet S–10 data over the years.

We appreciate all commenters' input and recommendations on how to improve our audit process and reiterate our commitment to continue working with the MACs and providers on audit improvements, including changes to increase the efficiency of the audit process and build on the lessons learned in previous audit years. Regarding commenters' requests for a standard audit timeline, we do not intend to establish a fixed timeline for audits across MACs at this time so that we can retain the flexibility to use our limited audit resources to address and prioritize audit needs across all CMS programs each year. We note that MACs work closely with providers regarding scheduling dates during the Worksheet S–10 audit process.

Regarding commenters' requests that we make public the audit instructions and criteria, as we previously stated in the FY 2021 IPPS/LTCH final rule (85 FR 58822) and prior rules, we do not make review protocols public as CMS desk review and audit protocols are confidential and are for CMS and MAC use only. Concerning the request that we promulgate the Worksheet S–10 audit policy and protocols through notice and comment rulemaking, we do not believe it would be appropriate to seek comment on audit protocols that are confidential. Rather, it is sufficient that we provide stakeholders with notice of our proposed methodology for determining uncompensated care payments and the data sources that will be used, so that they may have a meaningful opportunity to submit their views on the proposed methodology and the adequacy of the data for the intended purpose.

Regarding commenters' recommendations that we establish a timely review and appeals process for the Worksheet S–10 audits, we do not intend on introducing such a process at this time in order to maximize limited audit resources. However, we will continue to work with stakeholders to address their concerns regarding the accuracy and consistency of data reported on Worksheet S–10. We will also continue to work with the MACs each year to further improve the consistency of the audit process across providers and MACs.

Concerning the suggestion to implement a fatal edit on Worksheet S–10, we note that we did not propose any additional edits to Worksheet S–10 data in the FY 2022 IPPS/LTCH PPS proposed rule. Furthermore, we continue to believe that the ongoing MAC reviews of hospitals' Worksheet S–10 data coupled with our efforts to improve reporting through revised instructions, as well as providers' growing experience with reporting uncompensated care costs outweigh the value of any ''fatal'' edits to the Worksheet S–10 data.

Concerning the commenter's request that we apply the same audit criteria that are used for empirically justified DSH payments, those audit protocols are also confidential and are for CMS and MAC use only. As explained previously, we continue to believe that audit protocols (for example, criteria) should be confidential, so we disagree with the commenter about making public any audit protocols. To the extent that the commenter is implying that the confidentiality of the audit protocols causes inconsistency in auditing across the MACs, we also disagree and will continue to work with the MACs each year to ensure a consistent audit process across providers and MACs.

The following comments relate to the Worksheet S–10 cost report instructions:

Comment: With regard to Worksheet S–10 instructions, a commenter appreciated the effort CMS has undertaken to improve the clarity of the Worksheet S–10 instructions. Some commenters also offered suggestions for CMS' calculation of uncompensated care costs, including possible changes to Worksheet S–10. Specifically, a commenter mentioned that multiplying the CCR by copayment amounts written off as charity care significantly understates the cost of charity care as these amounts have already been reduced through rate negotiation with the payor. Accordingly, the commenter requested that CMS instruct hospitals to report copayments for insured patients that are to be written off as charity care in Column 2, line 20, thereby excluding them from costs reduced by the CCR. Another commenter requested that CMS clarify the instructions for line 29 of the Worksheet S–10 regarding non-Medicare bad debt for insured patients and urged the agency not to apply the CCR to these amounts, adding that making this change would be consistent with the way CMS treats non-reimbursed Medicare bad debt.

Another commenter observed that Worksheet S–10 fails to account for all patient care costs when determining uncompensated care costs by ignoring the costs hospitals incur in training residents, supporting physicians and professional services, and provider taxes related to Medicaid revenue. The commenter requested that the agency refine Worksheet S–10 to include these costs. In particular, the commenter suggested that in calculating the CCR, the agency ''use total of Worksheet A, column 3 lines 1 through 17, reduced by the amount of worksheet A–9, line 10, as the cost component; and use worksheet C, column 8, line 200, as the charge component.'' According to the commenter, implementing this change would incorporate additional patient care costs incurred by hospitals, such as Graduate Medical Education (GME). Similarly, another commenter requested that CMS include teaching costs in determining uncompensated care costs on line 30 of Worksheet S–10 because excluding these costs disproportionately affects teaching hospitals and academic medical centers.

In addition, a commenter suggested that just as unreimbursed costs for charity care patients are recognized as uncompensated care costs, so should the shortfall of state or local indigent care programs, adding that CMS should also refine Worksheet S–10 data on Medicaid shortfalls to better resemble actual shortfalls incurred by hospitals. To this end, the commenter recommended that a more accurate measure of Medicaid shortfalls could include the incorporation of GME costs in the CCR. Another recommendation was that CMS allow hospitals to reduce Medicaid revenues by intergovernmental transfers (IGTs), provider reimbursement taxes, or certified public expenditures (CPEs). While the commenter agreed that Medicaid shortfalls, as currently reported on Worksheet S–10, should not be included in the uncompensated care cost estimation, they added that these data will be increasingly useful for informational purposes as more individuals gain access to Medicaid coverage. Similarly, a couple of other commenters requested that CMS undertake additional efforts to include a hospital's Medicaid shortfalls by incorporating line 31 of Worksheet S–10 into the calculation of a hospital's uncompensated care costs in Factor 3.

A commenter stated that CMS should afford providers with ample opportunities to provide feedback and receive education on Worksheet S–10 instructions and requested that CMS clearly communicate regarding revisions to cost report instructions and cost report submission deadlines. The commenter further recommended that CMS provide additional outreach and educational materials to hospitals about Worksheet S–10. Another commenter encouraged CMS to postpone the implementation of revisions to form CMS–2552–10, Hospital and Health Care Complex Cost Report, to allow providers more time to implement the required operational changes that the revisions would entail.

Response: We appreciate commenters' concerns regarding the need for clarification of the Worksheet S–10 instructions, as well as their suggestions for form revisions to improve reporting. We reiterate our commitment to continuing to work with stakeholders to address their concerns regarding Worksheet S–10 instructions and reporting through provider education and further refinement of the instructions as appropriate. We also encourage providers to discuss with their respective MACs any questions regarding clarifications of instructions and/or reporting.

We continue to believe that our efforts to refine the instructions have improved provider understanding of the Worksheet S–10 and added clarity to the instructions, as noted by a commenter. We also recognize that there are continuing opportunities to further improve the accuracy and consistency of the information that is reported on the Worksheet S–10, and to the extent that commenters have raised new questions and concerns regarding the reporting requirements, we will attempt to address them through future rulemaking and/or provider outreach. However, as stated in previous rules, we continue to believe that the Worksheet S–10 instructions are sufficiently clear and allow hospitals to accurately complete Worksheet S–10.

Regarding the comments requesting specific structural changes to Worksheet S–10 and/or further clarification of the reporting instructions, as well as the recommendation that we postpone the implementation of revisions to Form CMS–2552–10 (OMB Control Number 0938–0050, expiration date March 31,

2022), we note that these comments fall outside the scope of this final rule. We therefore refer commenters to the forthcoming Paper Reduction Act (PRA) package comment period for the Worksheet S–10, which will be the appropriate forum to raise specific questions about or suggestions for modifications and clarifications to Worksheet S–10, including the reporting instructions.

For commenters' reference, additional materials regarding clarifications to the Worksheet S–10 instructions are contained in the MLN article titled ''Updates to Medicare's Cost Report Worksheet S–10 to Capture Uncompensated Care Data'', available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/se17031.pdf*, as well as the Worksheet S–10 Q&As on the CMS DSH website in the download section, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/Worksheet-S-10-UCC-QandAs.pdf*.

- IHS and Tribal Hospitals

For the reasons discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), we continue to recognize that the use of data from Worksheet S–10 to calculate the uncompensated care amount for IHS and Tribal hospitals may jeopardize these hospitals' payments due to their unique funding structure. Prior to the proposed rulemaking for FY 2022, CMS consulted with IHS and Tribal hospitals regarding uncompensated care reporting. We are considering the input received through this consultation with IHS and Tribal hospitals for future rulemaking.

Therefore, for IHS and Tribal hospitals, we proposed to continue the policy first adopted in the FY 2018 rulemaking regarding the low-income patient proxy. Specifically, for FY 2022 we proposed to determine Factor 3 for these hospitals based on Medicaid days for FY 2013 and the most recent available year of data on SSI days. The aggregate amount of uncompensated care that is used in the Factor 3 denominator for these hospitals would continue to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH eligible hospitals using the low-income insured days proxy. As we explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 24543), we continue to believe this approach is appropriate because the FY 2013 data reflect the most recent available information regarding these hospitals' Medicaid days before any expansion of Medicaid. We also note that all IHS and Tribal hospitals have a FY 2013 cost report that can be used for purposes of determining Factor 3. At the time of development of the proposed rule, for modeling purposes, we computed Factor 3 for these hospitals using FY 2013 Medicaid days from a HCRIS extract updated through February 19, 2021, and the FY 2018 SSI days.

Comment: Commenters expressed support for CMS' proposal to continue using low-income patient days as a proxy to calculate Factor 3 IHS and Tribal hospitals for FY 2022, with a commenter suggesting the use of the proxy in future years as well. Another commenter recommended that in subsequent years CMS allow Indian Health Care Provider (IHCP) hospitals the option of continuing to use the low-income days proxy measure or data from Worksheet S–10 to calculate uncompensated care amounts for the purposes of determining uncompensated care payments. Several commenters reiterated their support for a modified policy of paying Tribal and IHS hospitals 100% of Medicare DSH and requested that CMS explain why they did not propose this policy again.

A commenter also expressed dismay that CMS has yet to address the concerns previously mentioned with regard to the application of the uncompensated care cost policy to IHS and Tribal hospitals. The commenter requested that at a minimum, CMS give stakeholders one year to provide comments on a proposed policy and allow an additional three years as an implementation phase for the newly developed methodology.

The commenter indicated that, in the event uncompensated care payments for IHS and Tribal hospitals were to be determined using Worksheet S–10 data, 26 facilities with less than 100 beds would stand to collectively lose $7.5 million in DSH payments, while the two largest facilities would stand to gain $6.9 million. The commenter also noted that only two IHS and Tribal hospitals, both of which have more than 100 beds, would not be subject to the 12 percent cap on DSH payments. They recommended that CMS remove the 12 percent cap as this ''would advance the intent of the Congress to maximize Federal resources for the Indian health system.'' The commenter added that if the 12 percent cap cannot be addressed via a statutory fix, CMS should work with hospitals to adopt changes to the methodology for calculating uncompensated care and charity care that address the unique circumstances of the Indian health system so that the disproportionate impact of the cap is offset. Further, while the commenter recognized that the cap ''is statutorily imposed by the MMA [Medicare Modernization Act] and that CMS cannot act unilaterally to change it,'' they proposed that the agency work with Congress to remove the cap from all IHS and Tribal hospitals.

The commenter also noted that IHS and Tribal Hospitals also face a unique legal standing such that they do not ''fit well into the framework that CMS is proposing to adjust for uncompensated care payments.'' The commenter added that the inability to charge any Indian for services, including copays, and the provisions contained within treaties with the Federal Government and judicial rulings, mean that these hospitals are subject to a very unique method of calculating uncompensated care costs. The commenter maintained that the calculation of uncompensated care payments should be done in such a way as to maximize these hospitals' access to Federal resources. The commenter suggested that CMS work with IHS and Tribal facilities as well as the consortium to provide guidance on how these facilities should report uncompensated care on Worksheet S–10. In this regard, another commenter expressed that a significant challenge for IHS and Tribal hospitals is that CMS may be interpreting that ''IHCPs do not have uncompensated care costs under Worksheet S–10, because base funding for the costs of patient care is provided through Congressional appropriations and might construe this as all care being considered compensated.'' However, commenters state that IHS appropriations do not fully fund the costs of care and that many tribal health programs invest non-Federal resources ''to furnish care that could easily be classified as uncompensated care since IHCPs may not charge beneficiaries to receive care and, thus, may not have the accounting methods to track these costs.'' In summary, the commenter stated that IHCP hospitals are currently unable to report charity care and non-Medicare bad debt in a way that is consistent with the definition of uncompensated care in the regulation.

Additionally, a commenter stated that the information technology systems used by IHS and Tribal hospitals are not equipped to collect the necessary data for the Worksheet S–10, noting that while IHS recently received funding to upgrade its information technology system, it will take some time, potentially years, before it is fully functional. The commenter urged CMS to work and consult with IHS to develop any new proposed methodology for

calculating uncompensated and charity care for IHS and Tribal hospitals that would be used as an alternative to Worksheet S–10 to ensure that it accurately captures uncompensated and charity care provided by these facilities. Another commenter requested that CMS take additional time to work with the Tribal Technical Advisory Group and IHS and Tribal hospitals in the event it transitions these facilities to a new payment methodology for the calculation of Medicare DSH payments.

Response: We also appreciate the concerns raised and the input offered by commenters regarding the methodology for calculating uncompensated care payments for IHS and Tribal hospitals. We continue to recognize the unique nature of these hospitals and the special circumstances IHS and Tribal hospitals face, and we reiterate our commitment to continue working with stakeholders, including through tribal consultation, as we revisit the issue of Medicare uncompensated care payments to these hospitals for the FY 2023 rulemaking. We are not making any changes to the current policy for calculating uncompensated care payments for IHS and Tribal hospitals at this time, and we look forward to continuing to collaborate on methodological approaches in the future.

After consideration of the comments received, we are finalizing our proposal to use the low-income insured days proxy to determine Factor 3 for IHS and Tribal hospitals for FY 2022.

- Puerto Rico Hospitals

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to determine Factor 3 for Puerto Rico hospitals using Worksheet S–10 data starting in FY 2022. We did not finalize this proposal in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58825) because we believed further consideration was necessary. However, we noted that we continued to believe Worksheet S–10 data is the appropriate long-term source for information on uncompensated care for hospitals located in Puerto Rico.

As explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25453), we are continuing to consider the reporting challenges in Puerto Rico that may negatively impact the ability of Puerto Rico hospitals to report uncompensated care. Accordingly, for FY 2022 we proposed to determine Factor 3 for Puerto Rico hospitals that have a FY 2013 cost report based on the low-income patient proxy. We would determine Factor 3 for these hospitals based on Medicaid days for FY 2013 and the most recent available year of data on SSI days. The aggregate amount of uncompensated care that is used in the Factor 3 denominator for these hospitals would continue to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH eligible hospitals using the low-income insured days proxy. At the time of development of the proposed rule, for modeling purposes, we computed Factor 3 for these hospitals using FY 2013 Medicaid days from a recent HCRIS extract and the most recent available data on SSI days, which was the FY 2018 SSI days. In addition, because we proposed to continue to use 1 year of insured low-income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we proposed to continue to use a proxy for SSI days for Puerto Rico hospitals, consisting of 14 percent of a hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

Comment: Several commenters supported CMS' proposal to continue the use of low-income days as a proxy for hospitals located in Puerto Rico for FY 2022. Commenters also supported the use of 14 percent of a hospital's Medicaid days to determine SSI days for hospitals in Puerto Rico, as finalized in the 2017 Inpatient IPPS/LTCH PPS final rule. A commenter noted that using the Worksheet S–10 to calculate uncompensated care costs for hospitals located in Puerto Rico would have a severe, unfavorable economic effect, which would exacerbate the already precarious financial conditions these hospitals face. This commenter suggested that CMS consider allowing a period of at least four to five years under the low-income days proxy to evaluate the ''advancement done in the accounting methodology and reimbursement factor for PR [Puerto Rico].''

According to the commenter, a transition to the Worksheet S–10 would risk the financial stability of 40 percent of hospitals in Puerto Rico, which have already incurred significant losses as a result of the COVID–19 pandemic. The commenter expressed concern that the Worksheet S–10 has an ''implied penalty'' for Puerto Rico hospitals due to their low-cost structure as compared to higher cost hospitals located in the mainland US., adding that using Worksheet S–10 to calculate Factor 3 would not account for the deficiency in Medicaid reimbursement for Puerto Rico Hospitals. The commenter also stated that Puerto Rico's government health program, known as VITAL, covers approximately 1.2 million inhabitants of the total 3 million population of Puerto Rico. The commenter stated that ''several services not paid by the insurance companies contracted by the Puerto Rico Government to provide services to VITAL's beneficiaries are absorbed by the hospital because the coverage provided by VITAL does not allow the hospital to collect such unpaid services from the patient.'' Additionally, the commenter stated that currently some hospitals in Puerto Rico do not have a charity care policy, even though they provide charity care services. Instead, these services are often inappropriately accounted for as a ''contractual adjustment.'' The commenter further explained that those hospitals in Puerto Rico with a charity care policy in place do not know how to optimize their accounting systems to accommodate such policies, adding that hospitals may also be inappropriately accounting for bad debts. The commenter concluded that all of these factors understate the components of uncompensated care costs, and that technical education is needed to address the challenges Puerto Rico hospitals have regarding charity care and bad debt reporting, which would take years to address.

Response: We appreciate the concerns raised by commenters regarding the calculation of Factor 3 for hospitals in Puerto Rico. Regarding the recommendation that we provide Puerto Rico hospitals a 4- to 5-year continuation of the current policy before the transition to the use of Worksheet S–10, we continue to invite commenters to provide further input as we revisit the use of Worksheet S–10 data from Puerto Rico hospitals in the Factor 3 methodology in future rulemaking and assess the results of FY 2019 audits for these hospitals. We will consider the commenters' concerns regarding the unique financial circumstances and challenges faced by Puerto Rico hospitals related to uncompensated care cost reporting on Worksheet S–10 in future rulemaking as appropriate.

After consideration of the comments received, we are finalizing the use of low-income insured days proxy to determine Factor 3 for Puerto Rico hospitals for FY 2022.

(b) Methodology for Calculating Factor 3 for FY 2022

As we explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25454), for purposes of determining Factor 3 for FY 2022, we are applying the methodology adopted in the FY 2021 IPPS/LTCH PPS final rule. Specifically, we are applying the following policies: (1) The merger policies that were

initially adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021), as modified in the FY 2021 IPPS/LTCH PPS final rule to incorporate the use of a multiplier to account for merger effective date; (2) the policy for providers with multiple cost reports, beginning in the same fiscal year, of using the longest cost report and annualizing Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (3) the policy, as modified in the FY 2021 IPPS/LTCH PPS final rule, for the rare case where a hospital has a cost report that starts in one fiscal year and spans the entirety of the following fiscal year, such that the hospital has no cost report for that subsequent fiscal year, of using the cost report that spans both fiscal years for the latter fiscal year; (4) the new hospital policy, as modified in the FY 2020 IPPS/LTCH PPS final rule; (5) the newly merged hospital policy; and (6) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10.

Comment: A commenter noted that CMS' policy of annualizing the data for the longest cost report period for a hospital in a fiscal year disadvantages providers who have undergone a change in ownership (CHOW). According to the commenter, there are cases when the hospital undergoes a CHOW in the later part of their 12-month cost reporting period, and in such cases the first stub-period's uncompensated care costs would be annualized for purposes of calculating Factor 3. The commenter notes that this approach poses a problem because the annualized stub-period would understate the hospital's uncompensated care as compared to the full combination of pre- and post-CHOW reports due to ''significant presumptive charity write-offs occurring in the last month of the 2nd stub period [not annualized].'' The commenter provided an example of such case, where a hospital's Factor 3 was understated by 20 percent under the current policy of annualizing the longest cost report.

The commenter also noted that the use of annualization may understate or overstate a hospital's uncompensated care due to seasonal fluctuations, and that in the event of a CHOW, such annualization would not be needed if both cost report stubs, pre- and post-CHOW, would equal 12 months. The commenter also provided analysis that demonstrated significant uncompensated care payment impacts, both positive and negative, due to the current policy (only the longest cost report stub would be utilized for hospitals that underwent a CHOW) as compared to combining stub-period cost reports that account for all 12 months.

To address these issues, the commenter requested that CMS utilize a combined stub-period cost report that accounts for all 12 months of uncompensated care data for hospitals that have undergone CHOWs but maintained their fiscal year ends when calculating Factor 3.

Response: We thank the commenter for expressing their concerns and suggestions. We believe that the current policy of using the longest cost report available in a fiscal year for a hospital and annualizing its data meets, in practice, the policy goals of adjusting uncompensated care costs for purposes of the Factor 3 calculation. In addition, given that CHOWs are not mergers, we do not, at this time, consider it necessary to combine data across cost reports. There are also inherent issues in combining cost reports for CHOW hospitals in that, as the commenter noted, the true annual volume of uncompensated care for some providers could be overestimated or underestimated as a result. We believe CHOWs and the timing of charity write-offs are hospital business decisions. We also note that we did not propose any changes to the policy for providers with multiple cost reports; and, we would want to collect additional input and suggestions from stakeholders before considering making any potential modifications or refinements to the current policy for hospitals with multiple cost reports in future rulemaking. Therefore, we are not adopting the commenter's recommendation at this time.

- New Hospital for Purposes of Factor 3

We are continuing to apply the new hospital policy that was initially adopted in the FY 2020 IPPS/LTCH PPS final rule to determine Factor 3 for new hospitals that do not have an FY 2018 cost report to use in the Factor 3 calculation (that is, hospitals with CCNs established on or after October 1, 2018). In the FY 2020 IPPS/LTCH PPS final rule, we modified the new hospital policy that was initially adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643) and continued to apply through FY 2019 (83 FR 41417). Under this modified policy, if a new hospital has a preliminary projection of being eligible for DSH payments based on its most recent available disproportionate patient percentage, it may receive interim empirically justified DSH payments. However, new hospitals will not receive interim uncompensated care payments during FY 2022 because we will have no FY 2018 uncompensated care data on which to determine what those interim payments should be. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2022 cost report. If the hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2022, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2022 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2018 cost reports for all DSH-eligible hospitals. This denominator will be the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals, with the exception of Puerto Rico hospitals and IHS and Tribal hospitals.

- Newly Merged Hospitals

We are continuing to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year will be recalculated similar to new hospitals (79 FR 50021 and 50022). Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, we will continue to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement. The numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, the data from the newly merged hospital's cost

report will be annualized for purposes of the Factor 3 calculation.

Consistent with past policy, interim uncompensated care payments for the newly merged hospital will be based only on the data for the surviving hospital's CCN available at the time of the development of the final rule. In other words, the eligibility of a newly merged hospital to receive interim uncompensated care payments for FY 2022 and the amount of any interim uncompensated care payments, will be based only on the FY 2018 cost report available for the surviving CCN at the time the final rule is developed. However, at cost report settlement, we will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2022 cost report. That is, we will revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2022 cost report.

Comment: A commenter supported the policy of making interim uncompensated care payments to newly merged hospitals based on the surviving hospital's cost report for FY 2018 and then determining the final uncompensated care payment for these hospitals at cost report settlement based on the FY 2022 cost report for the merged hospital. The commenter also supported the continuation of our current policy for determining uncompensated care payments for new hospitals.

Response: We appreciate the commenter's support for these policies. We are not making modifications to our existing policy regarding newly merged hospitals.

• CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). Consistent with the process for trimming CCRs used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831 and 58832), we apply the following steps to determine the applicable CCR:

Step 1: Remove Maryland hospitals. In addition, we remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: For FY 2018 cost reports, calculate a CCR ''ceiling'' with the following data: for each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report will be selected.) The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2018 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for FY 2018 greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling''). For both the proposed rule and this final rule, the statewide average CCR was applied to 10 hospitals, of which 3 hospitals had FY 2018 Worksheet S–10 data.

Step 5: For providers that did not report a CCR on Worksheet S–10, Line 1, we assign them the statewide average CCR as determined in step 3.

After completing the previously described steps, we re-calculate the hospital's uncompensated care costs (Line 30) using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

• Uncompensated Care Data Trim Methodology

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25455), we noted that after applying the CCR trim methodology there are rare situations where a hospital has potentially aberrant data that are unrelated to its CCR. Therefore, under the trim methodology for potentially aberrant UCC that was included as part of the methodology for purposes of determining Factor 3 in the FY 2021 final rule (85 FR 58832), if the hospital's uncompensated care costs for FY 2018 are an extremely high ratio (greater than 50 percent) of its total operating costs, we will determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs. Specifically, if the hospital's FY 2018 cost report is determined to include potentially aberrant data, data from the FY 2019 cost report will be used for the ratio calculation. Thus, the hospital's uncompensated care costs for FY 2018 will be trimmed by multiplying its FY 2018 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2019 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2018 for purposes of determining Factor 3 for FY 2022.

As we noted in the proposed rule, we have audited the FY 2018 Worksheet S–10 data for a number of hospitals. Because the UCC data for these hospitals have been subject to audit, we believe there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, consistent with the policy that was adopted in the FY 2021 IPPS/LTCH PPS final rule, it is unnecessary to apply the trim methodology for these audited hospitals.

In addition to the existing UCC trim methodology, we proposed to apply a new trim specific to certain hospitals that do not have audited FY 2018 Worksheet S–10 data. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25455), we noted that in rare cases, hospitals that are not currently projected to be DSH eligible and that do not have audited Worksheet S–10 data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). We proposed to use a threshold of three standard deviations from the mean ratio of insured patients' charity care costs to total uncompensated care costs (line 23 column 2 divided by line 30) and a dollar threshold of $7 million, which is the median total uncompensated care cost reported on FY 2018 cost reports for hospitals that are projected to be DSH eligible, excluding IHS and Tribal hospitals and Puerto Rico hospitals. Therefore, for FY 2022, we proposed that in the rare case that a hospital's insured patients' charity care costs are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent (rounded from 58 percent), we would exclude the hospital from the prospective Factor 3 calculation. This proposed trim would only impact hospitals that are not currently projected to be DSH eligible;

and therefore, are not part of the calculation of the denominator of Factor 3, which includes only uncompensated care costs for projected DSH eligible hospitals. If a hospital would be trimmed under both the existing UCC trim methodology and this proposed new trim, we proposed to apply this new trim in place of the existing UCC trim methodology. We explained that we believe the proposed new trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the existing trim, because the existing trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs.

In addition, we also proposed that, for the hospitals that would be subject to the proposed trim, if the hospital is ultimately determined to be DSH eligible at cost report settlement, then the MAC would calculate a Factor 3 after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2022 cost report. We believe if a hospital subject to this proposed trim is ultimately determined to be DSH eligible at cost report settlement, its uncompensated care payment should be calculated only after the hospital's reporting of insured charity care costs on its FY 2022 Worksheet S–10 has been reviewed. We note that this approach is comparable to the policy for new hospitals for which we cannot calculate a prospective Factor 3 because they do not have Worksheet S–10 data for the relevant fiscal year.

Comment: A commenter supported the policy not to adjust uncompensated care costs from hospitals that have been audited and found in compliance by their MAC and encouraged CMS to work with MACs to distinguish between inaccurate and legitimate values. Another commenter supported the proposed policy of trimming potentially aberrant charity care cost data from hospitals that are currently not projected to be DSH eligible and do not have audited FY 2018 Worksheet S–10 data by excluding the hospital from the prospective Factor 3 calculation.

Response: We appreciate the commenters' support. We reiterate our continued efforts to work with the MACs to improve the accuracy of the uncompensated care costs reported on Worksheet S–10. After consideration of the comments received, we are finalizing the proposed policy for trimming potentially aberrant charity care costs for hospitals that are not projected to be DSH eligible and that do not have an audited Worksheet S–10 for FY 2018.

- Summary of Methodology

In summary, for FY 2022, we will compute Factor 3 for each hospital using the following steps:

Step 1: Select the provider's longest cost report from its Federal fiscal year (FFY) 2018 cost reports. (Alternatively, in the rare case when the provider has no FFY 2018 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2018 time period, the previous Federal fiscal year cost report will be used in this step.)

Step 2: Annualize the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013 using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals.

Step 5: Calculate Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2018 cost report data (from Step 1, 2 or 3). New hospitals and the hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We proposed to amend the regulation at § 412.106 by adding a new paragraph (g)(1)(iii)(C)(*9*) to reflect the methodology for computing Factor 3 for FY 2022 for IHS and Tribal hospitals and for Puerto Rico hospitals that have a 2013 cost report. We also proposed to make a conforming change to limit the reference to Puerto Rico hospitals in paragraph (g)(1)(iii)(C)(8) to those Puerto Rico hospitals that have a cost report for 2013.

Comment: A couple of commenters recommended that CMS use the traditional payment reconciliation process to calculate final payments for uncompensated care costs pursuant to section 1886(r)(2) of the Act. These commenters did not object to CMS using prospective estimates, derived from the best data available, to calculate interim payments for uncompensated care costs. However, the commenters stated that interim payments should be subject to later reconciliation based on estimates derived from actual data from the applicable Federal fiscal year. The commenters also noted that not all FY 2018 Worksheet S–10 cost reports were audited and that the use of a blend of audited and unaudited data would be arbitrary and inconsistent with the statutory requirements. These same commenters also expressed the need for meaningful engagement on concerns raised in the rulemaking process and stated that the statutory preclusion of review leaves intact the agency's responsibilities, including the rulemaking requirements of the Administrative Procedure Act and the Medicare Act.

Response: Consistent with the position that we have taken in rulemaking for previous years, we continue to believe that applying our best estimates of the three factors used in the calculation of uncompensated care payments to determine payments prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; 82 FR 38195; and 84 FR 42373). We continue to believe that, in affording the Secretary the discretion to estimate the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree with the commenter's suggestion that we should establish a process for reconciling our estimates of uncompensated care payments, which would be contrary to the notion of prospectively. Furthermore, we note that this rulemaking has been conducted consistent with the requirements of the Administrative Procedure Act and Title XVIII of the Act. Under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2022 IPPS/LTCH PPS proposed rule included a detailed discussion of the methodology for calculating Factor 3 for FY 2022 and the data that would be used. All proposed modifications to the methodology that was adopted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833) for FY 2021 and subsequent fiscal years were discussed in detail in the proposed rule, and we solicited comments on the proposed methodology for FY 2022 (86

FR 25457). We made public the best data available at the time of the proposed rule, in order to allow hospitals to understand the anticipated impact of the proposed methodology and to submit comments, and we have considered those comments in determining our final policies for FY 2022.

Comment: A commenter urged CMS not to use the HCRIS extract from March 2021 to calculate the final Factor 3 for FY 2022, mentioning that in the proposed rule, the agency indicated it would consider using a later HCRIS extract for the purposes of calculating the final Factor 3 for the FY 2022 IPPS/LTCH PPS final rule. According to the commenter, it would be appropriate to use a later HCRIS extract considering the ''last minute'' Worksheet S–10 audit adjustments made by the MACs, which were made beyond CMS' expected timeframe of using a December 2020 HCRIS extract for the FY 2022 proposed rule and a March HCRIS extract for the FY 2022 final rule. The commenter asserted that due to these delayed adjustments, they did not have ample time to scrutinize the data. Additionally, the commenter provided their analysis regarding reports with changes to Worksheet S–10 data between the December 2020 and March 2021 HCRIS extracts; specifically, the commenter stated that 15 percent of hospitals eligible for uncompensated care payments received a negative adjustment, which the commenter believed warrants using more recent, accurate cost report extract.

Response: We appreciate the commenter's concerns regarding the HCRIS extract proposed for use in the FY 2022 IPPS/LTCH final rule. We also agree with the commenter's recommendation on using a later HCRIS extract for calculating Factor 3 for FY 2022. We recognize that at the time of the March HCRIS extract, MACs were resolving inadvertent report upload discrepancies, which delayed the availability of the most up-to-date reports with audited Worksheet S–10 data for some hospitals. For example, there was a delay in uploading some amended reports to incorporate Worksheet S–10 audit results. Therefore, we are finalizing the use of the June 30 HCRIS extract to calculate Factor 3 for this FY 2022 IPPS/LTCH PPS final rule. We believe on balance this is the best available data for purposes of calculating Factor 3 for FY 2022.

Additionally, in the rare situations where a MAC mishandled a report in the upload process (such as, by accepting an amended report, reopening a report, and/or adjusting uncompensated care cost data on a report, but the corrected uncompensated care cost data were inadvertently omitted from the June 30, 2021 extract of the HCRIS), we used the corrected version of the report after confirming the appropriate report version with the applicable MAC.

We note that for purposes of Factor 3 calculations for future years, we still intend to use the most recent data available for the applicable rulemaking, which generally means the respective December HCRIS extract for purposes of future proposed rules. We expect that the December HCRIS extract would reflect the completed Worksheet S–10 audit results available in time for development of the proposed rule for the applicable fiscal year and that the respective HCRIS extract public use files, which are posted on the CMS website quarterly, would include the most recent audited cost report information for the applicable fiscal year, and be available for public scrutiny. Furthermore, as noted in the FY 2022 IPPS/LTCH PPS proposed rule, we intend to use the respective March HCRIS for future final rules, because we believe audited Worksheet S–10 data from FY 2019 reports will be available before the development of the FY 2023 proposed rule and final rule.

(c) Per Discharge Amount of Interim Uncompensated Care Payments

Since FY 2014, we have made interim uncompensated care payments during the fiscal year on a per discharge basis. We have used a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount for the applicable fiscal year, is divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine the uncompensated care payment per discharge for that fiscal year.

We proposed to modify this calculation for FY 2022 to be based on the average of FY 2018 and FY 2019 historical discharge data, rather than a 3-year average that includes data from FY 2018, FY 2019, and FY 2020. We explained our belief that computing a 3-year average with the FY 2020 discharge data would underestimate discharges, due to the decrease in discharges during the pandemic. Under the proposed approach, the resulting 2-year average of discharges would be used to calculate the per discharge payment amount that will be used to make interim uncompensated care payments to each projected DSH eligible hospital during FY 2022. The interim uncompensated care payments made to a hospital during the fiscal year are reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the Federal fiscal year.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), we finalized a voluntary process through which a hospital may submit a request to its MAC for a lower per discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the Federal fiscal year and/or once during the Federal fiscal year. In conjunction with this request, the hospital must provide supporting documentation demonstrating there would likely be a significant recoupment (for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000) at cost report settlement if the per discharge amount is not lowered. For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per discharge uncompensated care payment amount. As another example, a hospital might request that its per discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

Under the policy we finalized in the FY 2021 IPPS/LTCH PPS final rule, the hospital's MAC would evaluate these requests and the supporting documentation before the beginning of the Federal fiscal year and/or with midyear requests when the historical average number of discharges is lower than hospital's projected FY 2022 discharges. If following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that will be made is to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. If the MAC determines it would be appropriate to reduce the interim Medicare uncompensated care payment per discharge amount, that updated amount

will be used for purposes of the outlier payment calculation for the remainder of the Federal fiscal year. We refer readers to the Addendum to the proposed rule for a more detailed discussion of the steps for determining the operating and capital Federal payment rate and the outlier payment calculation. No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, any change to the per discharge uncompensated care payment amount will not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

Comment: Several commenters expressed support for the proposed policy of using the average of FY 2018 and FY 2019 discharge data, rather than a three-year average, which would also include FY 2020 discharges. The commenters agreed that this change is appropriate in light of the COVID–19 PHE.

Response: We thank commenters for their support. We are finalizing our proposal to modify the methodology used to estimate a hospital's average number of discharges to be based on FY 2018 and FY 2019 historical discharge data, rather than a 3-year average that includes data from FY 2018, FY 2019, and FY 2020. We agree with commenters that including FY 2020 discharge data would underestimate discharges due to the effects of the COVID–19 PHE.

Comment: A commenter recommended that CMS apply a growth factor to the claims average in the DSH Public Use File, in order to account for the growth in Medicare eligible population due to aging baby boomers. According to the commenter, the growth factor could be based on ''calculating the growth in Part A fee-for-service average monthly enrollment'' from Congressional Budget Office (CBO) published estimates. Based on the commenter's calculations, the growth factor could be 1.08, which is the quotient from dividing 66 million Part A beneficiaries in 2022 by 61 million in 2019.

The commenter also requested that the agency establish a limit on the estimated per claim amount due to exorbitant per-claim values of up to $117,599. The commenter stated that such amounts could produce significantly high coinsurance charges for Medicare Advantage (MA) beneficiaries if services are rendered out-of-network, which could exceed an MA beneficiary's out-of-pocket maximum. The commenter also mentioned that the approach of determining per-discharge uncompensated care payments based on Medicare patient volumes rather than uncompensated care volumes produces cash flow swings for hospitals with significant amounts of uncompensated care but low Medicare patient volumes, resulting in interim uncompensated care payments that do not reflect the actual costs incurred by the hospital.

Regarding CMS' current policy under which hospitals may request that their MAC adjust per-claim payment amounts, the commenter stated that it seemed unlikely that hospitals would want to request a lower or zero per-claim uncompensated care payments because of inherent incentives to maximize their cash flow. To this end, the commenter recommends that CMS place a cap on the amount of the per-discharge interim uncompensated care payments ''within the range of $5,233–$10,466, which represents a range of one to two standard deviations of the Estimated Per Claim Amounts for all qualifying hospitals.''

Response: We thank the commenter for sharing their concerns and feedback. We continue to believe that allowing hospitals the opportunity of voluntarily requesting a decrease to the per-discharge amount of interim uncompensated care payments may facilitate greater payment predictability throughout the year and limit recoupment of overpayments as part of cost report settlement. Regarding the commenter's other suggestions, such as applying a growth factor as part of the per discharge calculation, we may consider this input for any potential modifications or refinements to our policy for determining interim uncompensated care payments in future rulemaking; however, at this time, we are not adopting any changes to the current policy.

(d) Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with this final rule, we will publish on the CMS website a table listing Factor 3 for all hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2022 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. However, we note that a Factor 3 will not be published for the hospitals that are subject to the new trim we are adopting in this final rule, which is similar to the approach for new hospitals, which also do not have a Factor 3 published. Although we noted in the FY2022 IPPS/LTCH PPS proposed rule, that if more recent data become available, then we would use such data in the final rule, at the time of development of this final rule, the FY 2019 SSI ratios were not available. Accordingly, for purposes of this final rule, we computed Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals using the most recent available data regarding SSI days from the FY 2018 SSI ratios.

We also will publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. In the DSH uncompensated care supplemental data file, we list new hospitals and the 8 hospitals that are subject to the new trim, with a N/A in the Factor 3 column. We note that two of the hospitals that were projected to be subject to the trim in the proposed rule, are no longer participating in the Medicare program.

Hospitals had 60 days from the date of public display of the FY 2022 IPPS/LTCH PPS proposed rule in the **Federal Register** to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of the Worksheet S–10 data during the report submission process (for example, report not reflecting audit results due to MAC mishandling or most recent report differs from previously accepted amended report due to MAC mishandling). We stated that comments raising issues that are specific to the information included in the table and supplemental data file could be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We indicated that we would address comments related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2022 IPPS/LTCH PPS final rule. All other comments submitted in response to our proposed policies for determining uncompensated care payments for FY 2022 must have been submitted in one of three ways found in the **ADDRESSES** section of the proposed rule before the

close of the comment period in order to be assured consideration. In addition, this CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs.

For FY 2022, we again proposed that hospitals would have 15 business days from the date of public display of the FY 2022 IPPS/LTCH PPS final rule in the **Federal Register** to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. We stated that any changes to Factor 3 arising from this review would be posted on the CMS website and would be effective beginning October 1, 2021. We also explained that we continue to believe that hospitals have sufficient opportunity during the comment period for the proposed rule to provide information about recent and/or pending mergers and/or to report upload discrepancies. Hospitals do not enter into mergers without advanced planning. A hospital can inform CMS during the comment period for the proposed rule regarding any merger activity not reflected in supplemental file published in conjunction with the proposed rule. As discussed in an earlier section of this final rule, we also stated that we expected to use data from the March 2021 HCRIS extract for the FY 2022 final rule, which contributed to our increased confidence that hospitals would be able to comment on mergers and report any upload discrepancies during the comment period for the proposed rule. However, we noted that we might consider using more recent data that may become available after March 2021, but before the final rule for the purpose of calculating the final Factor 3s for the FY 2022 IPPS/LTCH PPS final rule. In the event that there are any remaining merger updates and/or upload discrepancies after the final rule, the 15 business days from the date of public display of the FY 2022 IPPS/LTCH PPS final rule deadline should allow for the time necessary to prepare and make any corrections to Factor 3 calculations before the beginning of the Federal fiscal year.

Comment: A commenter notified CMS that in reviewing the DSH Supplemental File for the FY 2022 proposed rule, their merger was not listed and only one hospital was included in the file. The commenter requested assurance that the merger would appear in the FY 2022 final rule. Another commenter reported what it deemed to be an erroneous adjustment made by a MAC to copayment amounts that had been written off and had been reported on the Worksheet S–10 as charity care. The commenter urged CMS to reverse the adjustment made by the MAC to their uncompensated care costs for purposes of calculating Factor 3 in FY 2022.

Response: We appreciate the commenters' diligence in checking that their own reports and data were properly processed in DSH Public Use File. We have accounted for the merger and the report discrepancies identified by commenters, as appropriate, in the development of the DSH supplemental data file published in conjunction with this FY 2022 IPPS/LTCH PPS final rule, and we will continue to pay diligent attention to any data issues and work internally and with our contractors to resolve these issues in a timely manner. In regard to the merger notification, we thank the commenter for informing CMS of the merger activity not reflected in supplemental file published in conjunction with the proposed rule. Regarding the commenter reporting a disagreement related to Worksheet S–10 audit adjustments, as explained in the proposed rule, inquiries related to the audit process should be directed to the respective MAC.

After consideration of the comments received, we are finalizing our proposal to afford hospitals 15 business days from the public display of this FY 2022 IPPS/LTCH PPS final rule to submit comments on the accuracy of the supplemental data file, including with respect to mergers and/or report upload discrepancies. We also note that the historical FY 2018 cost reports are publicly available on a quarterly basis on the CMS website for analysis and additional review of cost report data, separate from the supplemental data file published with this final rule.

F. Counting Days Associated With Section 1115 Demonstration Projects in the Medicaid Fraction

We continue to review the large number of comments on the proposed revision to the regulation relating to the treatment of section 1115 waiver days for purposes of the DSH adjustment. Due to the number and nature of the comments that we received on our proposal, we intend to address the public comments in a separate document. We refer individuals interested in reviewing the background information and the discussion regarding these policies to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25457 through 25459).

G. Hospital Readmissions Reduction Program: Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, establishes the Hospital Readmissions Reduction Program. Under the Hospital Readmissions Reduction Program, Medicare payments under the acute inpatient prospective payment system (IPPS) for discharges from an applicable hospital, as defined under section 1886(d) of the Act, may be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare hospitals with respect to the proportion of beneficiaries who are dually eligible for Medicare and full-benefit Medicaid (''dually eligible beneficiaries'') in determining the extent of excess readmissions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676);
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401);
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676);
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048);
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543);
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979);
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240);
- FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439);
- FY 2020 IPPS/LTCH PPS final rule (84 FR 42380 through 42390); and
- FY 2021 IPPS/LTCH PPS final rule (85 FR 58844 through 58847).

We have also codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154. In section V.G.15 of the preamble of this final rule, we are updating the regulatory text at 42 CFR 412.154(f)(4) to add the phrase ''or successor website'' in order to reflect the change in the CMS website name

from Hospital Compare to Care Compare.

3. Summary of the Policies for the Hospital Readmissions Reduction Program

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25460 through 25462), we proposed to adopt a cross-program measure suppression policy due to the impact of the COVID–19 public health emergency (PHE) on quality measurement and pay-for-performance programs including the Hospital Readmissions Reduction Program. We also proposed to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) and we provided information on technical specification updates for the remaining five condition/procedure-specific readmission measures to exclude COVID–19 diagnosed patients from the measure denominators beginning in fiscal year (FY) 2023 (86 FR 25462 through 25464). Additionally, we proposed to use the MedPAR data to determine aggregate payments that aligns with the applicable period for FY 2022 (86 FR 25464 through 25465). We also proposed the automatic adoption of the use of MedPAR data corresponding to the applicable period beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary (86 FR 25465). In addition, we clarified our Extraordinary Circumstances (ECE) Policy (86 FR 25466 through 25468).

In this final rule, we are finalizing our proposals as proposed. We discuss these finalized proposals in greater detail in this final rule.

Finally, we requested public comment on possible future stratification of results by race and ethnicity for our condition/procedure-specific readmission measures and by expansion of standardized data collection to additional social factors, such as language preference and disability status (86 FR 25468 through 25469). We also sought comment in that section on mechanisms of incorporating other demographic characteristics into analysis that address and advance health equity, such as the potential to include administrative and self-reported data to measure co-occurring disability status.

4. Current Measures

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia; elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery.

We continue to believe the measures we have adopted adequately meet the goals of the Hospital Readmissions Reduction Program. However, due to the potentially substantial relationship between pneumonia and COVID–19, we proposed to suppress temporarily the inclusion of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) in the Hospital Readmissions Reduction Program measure set for the FY 2023 applicable period in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25462 through 25464). We also provided information on technical specification updates for the remaining five condition/procedure-specific readmission measures to exclude COVID–19 diagnosed patients from the measure denominators, including the Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505), the Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515), the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891), the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure Hospitalization (NQF #0330), and the Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) beginning in FY 2023 (86 FR 25464).

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439) for more information about how the Hospital Readmissions Reduction Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework. We refer readers to section IX.A of the proposed rule (86 FR 25549 through 25554), where we requested information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard (as described in that section). We also refer readers to section IX.B. of the proposed rule (86 FR 25554 through 25561), where we requested information on potentially expanding the scope of our methodology to adjust outcomes measurement to recognize disparities in care, to include statistically estimated race and ethnicity information.

5. Flexibility for Changes That Affect Quality Measures During a Performance Period in the Hospital Readmissions Reduction Program

In previous rules, we have identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating facilities' or practitioners' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 public health emergency (PHE), which has had and continues to have significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 PHE impedes effective quality measurement in several ways. Changes to clinical practices to accommodate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data used in quality measurement and the resulting quality scores. Measures used in the Hospital Readmissions Reduction Program need to be evaluated to determine whether their specifications need to be updated to account for new clinical guidelines, diagnoses or procedure codes, and medications that we have observed during the PHEs. Additionally, COVID–19 prevalence is not identical across the country, meaning that the medical provider community has been affected differently at different times throughout the calendar year. Under those circumstances, we remain significantly concerned that the Hospital Readmissions Reduction Program's quality measurement scores are distorted, which would result in skewed payment incentives and inequitable payments, particularly for hospitals that have treated more COVID–19 patients than others.

It is not our intention to penalize hospitals for performance on measures that are affected significantly by global events like the COVID–19 PHE. As previously discussed, the COVID–19 PHE has had, and continues to have,

significant and enduring effects on health care systems around the world, and affects care decisions, including readmissions to the hospital as measured by the Hospital Readmissions Reduction Program. As a result of the PHE, hospitals could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, reduced payments in the Hospital Readmissions Reduction Program. We are concerned that regional and temporal differences in COVID–19 prevalence during the FY 2022 and FY 2023 Hospital Readmissions Reduction Program applicable periods, which includes data collected during the PHE, have directly affected hospitals' readmissions measure performance for the FY 2022 and FY 2023 program years. Although regional and temporal differences in COVID–19 prevalence rates would not necessarily represent differences in the quality of care furnished by hospitals, they would directly affect the payment adjustments that these hospitals would receive and could result in an unfair and inequitable distribution in the assessment of penalties for excess readmissions. These inequities could be especially pronounced for hospitals that have treated a large number of COVID–19 patients.

Therefore, we proposed to adopt a policy for the duration of the PHE for COVID–19 that would enable us to suppress the use of quality measures via adjustment to the Hospital Readmissions Reduction Program's scoring methodology if we determined that circumstances caused by the COVID–19 PHE affected those measures and the associated ''excess readmissions'' calculations significantly (86 FR 25460 through 25462). Under the proposed policy, if we determined that the suppression of a Hospital Readmissions Reduction Program measure was warranted for a Hospital Readmissions Reduction Program applicable period, we would propose to calculate the measure's rates for that program year but then suppress the use of those rates to make changes to hospitals' Medicare payments. In the Hospital Readmissions Reduction Program, this policy would have the effect of temporarily weighting the affected measure at zero percent in the program's scoring methodology until adjustments were made, the affected portion of the performance period for the measure was made no longer applicable to program scoring, or the measure was removed entirely through rulemaking. We would still provide feedback reports to hospitals as part of program activities, including to inform their quality improvement activities, and to ensure that they were made aware of the changes in performance rates that we observed. We would also publicly report suppressed measures' data with appropriate caveats noting the limitations of the data due to the PHE for COVID–19.

In developing the proposed policy, we considered what circumstances caused by the PHE for COVID–19 would affect a quality measure significantly enough to warrant its suppression in a value-based purchasing program. We stated our belief that significant deviation in measured performance that can be reasonably attributed to the PHE is a significant indicator of changes in clinical conditions that could affect quality measurement. Similarly, we stated our belief that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 PHE, we stated our belief that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols could affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also noted that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new diseases or conditions. Finally, we stated our belief that, as evidenced during the COVID–19 PHE, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or facility-level case mix could result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believed should guide our determination of whether to suppress a Hospital Readmissions Reduction Program measure for one or more program years that overlap with the PHE for COVID–19. We proposed to adopt these Measure Suppression Factors for use in the Hospital Readmissions Reduction Program, and for consistency, the following value-based purchasing programs: Hospital VBP Program, HAC Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and End-Stage Renal Disease Quality Incentive Program. We stated our belief that these Measure Suppression Factors would help us evaluate the Hospital Readmissions Reduction Program's measures and that their adoption in the other value-based purchasing programs, as previously noted, would help ensure consistency in our measure evaluations across programs. We proposed Measure Suppression Factors as follows:

- Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.
- Rapid or unprecedented changes in—

++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

++ The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

- Significant national shortages or rapid or unprecedented changes in—

++ Healthcare personnel;

++ Medical supplies, equipment, or diagnostic tools or materials; or

++ Patient case volumes or facility-level case mix.

We also considered alternatives to the proposed policy that could also fulfill our objective to not hold hospitals accountable for measure results under the Program that are distorted due to the PHE for COVID–19. As previously noted, the country continues to grapple with the effects of the COVID–19 PHE, and in March 2020, CMS issued a nationwide, blanket ECE for all hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the COVID–19 PHE. This blanket ECE waived all data reporting requirements for Q1 and Q2 2020 data, including waiving the use of claims data and data collected through the CDC's web-based surveillance system for this data period, and quality data collection resumed on July 1, 2020. We considered extending this blanket ECE for Q3 and Q4 2020. This alternative would protect providers and suppliers from having their quality data used for quality scoring purposes in the event that such data had been affected significantly by the COVID–19 PHE. However, this option would make providers' quality data collection and reporting to CMS no longer mandatory and would leave no comprehensive data available for us to

provide confidential performance feedback to providers nor for monitoring and to inform decision-making for potential future programmatic changes, particularly if the PHE were extended.

As an alternative to the proposed quality measure suppression policy, we also considered not making any further changes to the program and implementing it as previously specified. However, this alternative would have meant assessing hospitals using quality measure data that had been significantly affected by the PHE for COVID–19. Additionally, given the geographic disparities in the COVID–19 PHE's effects, implementation of the program as previously finalized would place hospitals in regions that were more heavily affected by the PHE in Q3 and Q4 of 2020 at a disadvantage compared to hospitals in regions that were more heavily affected during the first two quarters of CY 2020.

We viewed this measure suppression proposal as a necessity to ensure that the Hospital Readmissions Reduction Program did not reward or penalize hospitals based on factors that the program's measures were not designed to accommodate. We intended for the proposed policy to provide short-term relief to hospitals if we determined that one or more of the Measure Suppression Factors warranted the suppression of one or more of the program's measures.

We invited public comments on this proposal for the adoption of a measure suppression policy for the Hospital Readmissions Reduction Program for the duration of the PHE for COVID–19, and also on the proposed Measure Suppression Factors that we developed for purposes of the proposed policy.

We also invited comment on whether we should consider adopting a measure suppression policy in the situation of a future national PHE, and if so, whether under such a policy, we should have the flexibility to suppress certain measures without specifically proposing to do so in rulemaking.

We also requested comment on whether we should in future years consider adopting any form of regional adjustment for the proposed measure suppression policy that could take into account any disparate effects of circumstances affecting hospitals around the country that would prompt us to suppress a measure. For example, COVID–19 affected different regions of the country at different rates depending on factors like time of year, geographic density, State and local policies, and health care system capacity. We also requested commenters' feedback on whether we should consider a suppression policy with more granular effects based on our assessment of the geographic effects of the circumstances, rather than suppress a measure completely by assigning it a 0 percent weight during any future PHEs. We asked commenters to discuss how region-based measure suppression could be accounted for within the program's scoring methodology.

We invited public comment on this proposal. The comments we received and our responses are set forth in this section of this rule.

Comment: Many commenters expressed support for our proposed measure suppression policy, agreeing with our stated goal of ensuring that hospitals are not rewarded or penalized for their quality performance based on non-representative data. Some commenters recommended that we ensure that the suppression policy does not unintentionally penalize hospitals.

Response: We thank the commenters for their support. We acknowledge commenters' concern that the suppression policy should not unintentionally penalize hospitals. As discussed in the proposed rule and in section V.G.6 of this final rule, we proposed to suppress the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) in the Hospital Readmissions Reduction Program due to the impacts of the COVID–19 PHE on this measure for purposes of scoring and payment adjustments because of our concern in the ability to make fair, national comparisons of hospitals across the country.

Comment: Several commenters expressed support for our proposal to provide confidential performance feedback to hospitals on suppressed measures.

Response: We thank the commenters for their support. We will provide confidential feedback reports to hospitals for the pneumonia readmission measure using the current specifications. In these confidential reports, hospitals will be able to see which of their patients were readmitted to the hospital, and which of their patients were excluded from the measure denominator to inform hospital quality improvement initiatives.

Comment: Some commenters expressed concerns about our proposed suppression policy. Some commenters suggested that we should limit this policy to the current PHE given the unique circumstances involved in the COVID–19 pandemic. A few commenters expressed concerns about CMS being empowered to implement scoring adjustments and payment changes outside of rulemaking, and worried that comparisons between suppressed and unsuppressed scores would be unfair.

Response: We thank the commenters for their feedback. We do not intend for this policy to implement subregulatory scoring adjustments or payment changes beyond the COVID–19 PHE. Any scoring adjustments or payment changes that might address a different, future fiscal year of the program due to the COVID–19 PHE or another type of public health emergency would be proposed through rulemaking. We view the COVID–19 PHE as exceptional and, as with the measure suppression proposal, we will continue to maintain our quality programs via rulemaking. We acknowledge the commenters' concerns about potentially unfair comparisons between suppressed and unsuppressed performance information, and will consider for future rulemaking any such issues we identify.

Comment: Several commenters stated that we should not publicly report suppressed data, suggesting that data unfit to determine payments should not be publicly reported, while others suggested that we should note clearly that any publicly-reported data has been affected by the COVID–19 PHE.

Response: We understand the commenters concern about publicly reporting measure data from during the PHE due to COVID–19. However, as noted previously in section V.G.5. of the preamble of this final rule, we will make clear in the public presentation of the data that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the COVID–19 PHE. Displaying this information will promote transparency on the impacts of the PHE due to COVID–19, and we will appropriately caveat the data in order to mitigate public confusion.

Comment: Several commenters recommended that we carefully study the effects of the measure suppression policy and the measure suppression factors to inform any suppression policies for future PHEs. Several commenters recommended that we work with stakeholders before adopting additional measure suppression policies or any subregulatory policy changes on this topic in the future, including any potential changes to the Measure Suppression Factors, and requested that we explain the effects of any changes to the Suppression Factors in detail. A commenter suggested that we continue monitoring the effects of COVID–19 on 2021 quality performance and consider updating measure specifications to exclude COVID–19 patients or change our risk adjustment models. Other commenters suggested that we closely

monitor the shorter performance periods, as well as the effects of the policy on future benchmarking, and that we assess the indirect effects that the COVID–19 PHE has had on all aspects of medical care delivery.

Response: We share commenters' concerns about the potential long-term effects of the measure suppression policy, including the measure suppression factors. We intend to work carefully with stakeholders before adopting any additional policies or policy changes on this topic in the future. We agree with commenters that we should monitor the COVID–19 PHE's ongoing effects carefully and we will work with measure developers to refine measure specifications as circumstances warrant. We will also assess performance periods, benchmarks, and other effects of the COVID–19 PHE carefully, and we will monitor the policy's effects as we implement it. We welcome stakeholders' continuing feedback as we continue responding to the PHE.

Comment: Some commenters expressed support for the proposed Measure Suppression Factors, while others suggested that we include more flexibility in the Suppression Factors, particularly to account for future PHEs, and that we consult with stakeholders when applying these factors in the future. A commenter recommended that we include more flexible language in our suppression factors to account for our evolving understanding of COVID–19.

Response: We thank the commenters for this feedback. While we appreciate the commenter's suggestion that we incorporate more flexibility into the current Measure Suppression Factors, we believe the specificity with which we proposed them was necessary to provide hospitals, patients/consumers, and other stakeholders with insight into the decision-making process that we employed in response to the COVID–19 PHE. However, we will also engage with stakeholders when developing and implementing these Suppression Factors for future PHEs.

Comment: Some commenters recommended that we refine our proposed Measure Suppression Factors. Some commenters suggested that we define them more precisely to be fully transparent with the factors' terms and effects, arguing that we have not defined what we consider to be ''significant'' deviation in national performance on a measure during a PHE. A commenter also argued that the Suppression Factors should be focused on effects on Medicare beneficiaries, not on providers or circumstances that may be within the control of providers. A commenter suggested that we consider suppressing measures for individual hospitals where performance may have deviated significantly from past performance, while another commenter recommended that we ensure that the Suppression Factors do not assess provider organizations' quality per se, but rather, the PHE at issue.

Response: We thank the commenters for this feedback. We believe that some level of discretion is necessary in the face of evolving circumstances like those that have confronted us in the COVID–19 PHE, which is why we have designed our Measure Suppression Factors to have a certain degree of flexibility as to the factors' terms and effects. In deciding which measures to suppress, and as discussed further in section V.G.6. of this final rule, we examined each measure and determined that the evidence showed deviation in the individual measure performance data associated with the COVID–19 PHE. We believe providing the evidence for the measure suppressions included in this final rule is transparent and provides sufficient explanation for our rationales. We note further that we designed several of the measure suppression factors to account for circumstances that could affect the health and safety of patients and healthcare personnel, and we believe that situations like personal protective equipment (PPE) shortages affect the care provided to Medicare beneficiaries. We recommend that any individual hospitals that believe that they have faced extraordinary circumstances that affect their quality performance that have not been addressed by the suppression policy, consider seeking an Extraordinary Circumstances Exception.[763]

Comment: Some commenters supported regional adjustments to the measure suppression policy, suggesting that we should account for disparate effects of circumstances like the COVID–19 pandemic around the country. Commenters requested that we seek stakeholders' feedback before adopting more granular suppression policies in the future. A commenter cautioned against regional adjustments, suggesting that such adjustments would not account for differences in PHE prevalence at safety-net hospitals that take on leading roles during PHEs.

Response: We thank the commenters for their feedback and will consider it for future rulemaking. We share the commenter's concern that adjustments to account for regional differences in a PHE's effects may not fully capture those differences.

After consideration of the public comments we received, we are finalizing our proposal to adopt a measure suppression policy and proposed Measure Suppression Factors for the duration of the COVID–19 PHE.

6. Provisions That Address the Impact of COVID–19 on Current Hospital Readmissions Reduction Program Measures

a. Background

On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President declared the COVID–19 pandemic a national emergency. On April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 21, 2021, and July 19, 2021, the Secretary renewed the January 31, 2020 determination that a PHE for COVID–19 exists and has existed since January 27, 2020. The Secretary may renew the PHE every 90 days until such time as the Secretary determines that a PHE no longer exists.

In response to the PHE for COVID–19, we have conducted analyses on the six current Hospital Readmissions Reduction Program measures to determine whether and how COVID–19 may have impacted the validity of these condition/procedure-specific readmission measures. For the reasons discussed in this section of this rule, we have concluded that COVID–19 has significantly impacted the validity of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) (hereafter referred to as the CMS 30-Day Pneumonia Readmission Measure (NQF #0506)), such that we cannot fairly assess this measure. The FY 2022 CMS 30-Day Pneumonia Readmission Measure (NQF #506) applicable period is July 1, 2017 through June 30, 2020. However, in the September 2020 IFC, we noted that we would except the use of any first or second quarter CY 2020 claims data from our calculation of performance for the applicable fiscal years (85 FR 54833). With this exception, the FY 2022 applicable period for this measure would only be affected by a shortened performance period (July 1, 2017 through December 1, 2019) that does not use data from the COVID–19 PHE. Therefore, we have determined that it is not necessary to suppress this measure for the FY 2022 program year. However,

[763] For more information regarding Extraordinary Circumstances Exceptions requests under the Hospital Readmissions Reduction Program, please see: *https://qualitynet.cms.gov/impatient/hrrp/participation#tab2.*

given the ongoing status of the PHE and the impact of COVID–19 on this measure data, we proposed to temporarily suppress this measure for the FY 2023 program year (86 FR 25462 through 25464).

We stated in the FY 2022 PPS/LTCH PPS proposed rule that although COVID–19 has also impacted the five remaining condition/procedure-specific measures, we have concluded that this impact is less severe overall and can be further mitigated by updating the measure specifications to exclude Medicare beneficiaries with a secondary diagnosis of COVID–19 (86 FR 25462). Therefore, we did not propose to suppress the five remaining condition/procedure-specific measures for the FY 2023 program year[764] but are updating their specifications instead (86 FR 25464). The measures are as follows:

- Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505);
- Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure Hospitalization (NQF #0330); and
- Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).

As discussed more fully later in this section of this final rule, we are modifying these five condition/procedure-specific measures to exclude COVID–19 patients from the measures as technical updates to the measure specifications.

b. Suppression of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 Program Year

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51664 through 51666), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 24490 through 24492) for information on our policies that relate to refinement of the readmissions measures and related methodology for the current applicable conditions/procedures.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25462 through 25464), we proposed to suppress temporarily the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 program year under proposed Measure Suppression Factor 2, clinical proximity of the measure's focus to the relevant disease or pathogen, particularly for a novel disease or pathogen of unknown origin, due to the COVID–19 PHE. COVID–19 is caused by the SAR–CoV–2 virus, which begins when respiratory droplets containing the virus enter an individual's upper respiratory tract.[765] Pneumonia has been identified as a typical characteristic of individuals infected with COVID–19,[766] and our analysis based on data from CY 2020 and early CY 2021 shows that a substantial portion of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) cohort includes admissions with a COVID–19 diagnosis. In addition, almost all of the patient admissions with a COVID–19 diagnosis have a principal diagnosis of sepsis; observed mortality rates for these admissions are extremely high and are substantially higher than admissions without a COVID–19 diagnosis. We are concerned that these higher mortality rates may also potentially distort readmissions data for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) cohort. Based on the currently available data for this measure, there is a substantial proportion of Medicare beneficiaries with a secondary diagnosis of COVID–19 in the measure cohort during CY 2020 and early CY 2021.

In accordance with the previously discussed measure suppression policy, we would weight the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) at zero percent in the Hospital Readmissions Reduction Program payment methodology such that claims data for this measure would not be used to assess that hospital's performance. Additionally, we would continue to monitor the claims that form the basis for this measure's calculations to evaluate the effect of the circumstances on quality measurement and to determine the appropriate policies in the future. We would also continue to provide feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that are observed and to inform quality improvement activities.

As previously discussed, the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) FY 2022 applicable period is July 1, 2017 through June 30, 2020. However, in the September 2020 IFC, we noted that we would not use any first or second quarter CY 2020 claims data to assess performance for the applicable fiscal years (85 FR 54833). With this exception, the FY 2022 applicable period for this measure would only be affected by a shortened performance period (July 1, 2017 through December 1, 2019) that does not use data impacted by the COVID–19 PHE. Therefore, we have decided that it is not necessary to suppress this measure for the FY 2022 program year. However, given the ongoing status of the PHE and the impact of COVID–19 on this measure's data, we proposed to temporarily suppress this measure for the FY 2023 program year.

Our analysis of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) claims data showed that a higher proportion of patients had a secondary diagnosis of COVID–19 than other readmission measures and that these patients have a higher risk of mortality than the remainder of the admissions in the pneumonia measure cohort.

[764] In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25462), we indicated that we were updating the five remaining condition/procedure-specific measures for the FY 2022 program year. However, as noted in our discussion above, in the September 2020 IFC we noted that we would except the use of any first or second quarter CY 2020 claims data from our calculation of performance for the applicable fiscal years (85 FR 54833). With this exception, the FY 2022 applicable period for these condition/procedure-specific readmission measures would only be affected by a shortened performance period (July 1, 2017 through December 1, 2019) that does not use data from the COVID–19 PHE. Therefore, we are updating in this final rule that we are modifying these condition/procedure-specific readmission measure specifications for the FY 2023 program year.

[765] CDC. ''How COVID–19 Spreads''. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[766] CDC. ''Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID–19)''. Updated February 16, 2021. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html*.

Table V.G-1: Percent of COVID-19 Diagnoses in Readmission Measure Cohorts, March – September 2020							
Readmission Measure Cohort	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020
Pneumonia	4.5	13.3	11.2	6.7	15.6	14.5	9.8
COPD	0.2	0.3	0.2	0.2	0.4	0.5	0.4
AMI	0.1	0.5	0.6	0.5	1.0	1.1	0.8
HF	0.1	0.4	0.6	0.6	0.7	0.8	0.7
THA/TKA	0.0	0.3	0.1	0.1	0.1	0.1	0.1
CABG	0.0	0.1	0.2	0.2	0.4	0.4	0.3

Data from September 2020 showed that although admission volumes for this cohort were substantially lower compared to admission volumes in September 2019, the observed readmission rates were statistically significantly higher compared to the observed readmission rates for this cohort during the same period in 2019.

Table V.G-2: Observed Readmissions Rate for Admissions with/without Secondary Diagnosis of COVID-19 Present on Admission (POA)			
	Number of Admissions	Number of Readmissions	Observed 30-Day Readmissions Rate
Admissions with Secondary Diagnosis of COVID-19 POA	6,421	793	12.4%
Admissions without a Diagnosis of COVID-19	59,435	9,389	15.8%

Our analyses performed with available data demonstrated that COVID–19 patients captured in the pneumonia readmission measure cohort likely represent a distinct, severely ill group of patients for whom it may be difficult to adequately ascertain appropriate risk adjustment. We want to ensure that the measure reflects care provided by the hospital to Medicare beneficiaries admitted with pneumonia and we are concerned that excluding a significant proportion of all eligible patients may not accurately reflect the care provided, particularly given the unequal distribution of COVID–19 patients across hospitals over time. Suppressing this measure for the FY 2023 program year would address this concern.

As part of our analysis, we also evaluated the impact of suppressing the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) on hospital eligibility, program calculations, and payment for the FY 2023 program year. We noted that we used data from the most recently completed performance period, FY 2021, to simulate removal of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) as compared to the baseline data.[767] We found that the suppression of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) resulted in about a 1 percent decrease in eligibility for hospitals with at least 25 eligible discharges for any of the readmission measures under the Hospital Readmissions Reduction Program; the number of hospitals receiving a payment reduction was reduced by 5.17 percent; the penalty as a share of payments, or the weighted average payment reduction decreased by .13 percentage points; and the estimated Medicare savings decreased by 22.20%. Therefore, we believe that suppressing the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) measure would have a minimal negative impact on eligibility for the Hospital Readmissions Reduction Program, and the number of hospitals receiving payment reductions. Although we noted that suppressing the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) measure would have larger impacts on the weighted average payment reduction and the estimated Medicare savings under the Hospital Readmissions Reduction Program, the reduction in penalty as a share of payments and estimated Medicare savings are expected based on the program methodology in which each measure contributes to the payment reduction additively, increasing the size of the payment reduction.

We sought comments on our proposal to suppress the current CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for FY 2023. The comments we received and our responses are set forth in this section of this rule.

Comment: Many commenters expressed support for our proposal to suppress the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for FY 2023. Several commenters noted that this suppression would help address the significant impact of the COVID–19 PHE

[767] We note that, for purposes of this analysis, we removed the pneumonia readmission measure from program results calculated using a 29-month performance period.

and the close clinical proximity of pneumonia to COVID–19, both of which could distort hospital performance on the measure. Several commenters also expressed support for not including the suppressed readmission measure in payment reduction calculations.

Response: We thank the commenters for their support.

Comment: Several commenters encouraged CMS to continue analyzing data from 2020 and 2021 to determine if suppression is necessary in future fiscal years due to the ongoing impact of the pandemic. A commenter noted that although they support suppression of the measure due to the COVID–19 PHE, the measures are intended to promote improvements in critical patient safety and quality of care metrics. For this reason, the commenter stressed the importance of resuming full implementation of hospital quality programs as soon as sufficiently reliable data are available.

Response: We thank the commenters for their feedback. We agree that the effects of the COVID–19 pandemic are ongoing and we will continue to monitor the claims that form the basis for this measure's calculations to evaluate the effect of the circumstances on quality measurement and to determine the appropriate policies in the future. We agree that it is important to continue tracking the impact of the COVID–19 PHE on the CMS 30-Day Pneumonia Readmission Measure (NQF #0506), as these data will inform our considerations regarding whether future measure suppression is necessary beyond FY 2023. We also agree that the measure is important to improving patient safety and quality of care, and will continue to monitor measure data to determine when it may be considered sufficiently reliable such that resuming full implementation of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) is appropriate.

Comment: Some commenters expressed concern regarding the public reporting of suppressed data, suggesting that data unfit to determine payments should not be publicly reported. A few commenters stated that such information should not be publicly reported because it would not be sufficiently accurate to support informed decision-making by beneficiaries and other stakeholders.

Response: We understand the commenters' concerns about publicly reporting measure data from during the PHE due to COVID–19. However, as noted previously in section V.G.5. of the preamble of this final rule, we will make clear in the public presentation of the data that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the PHE due to COVID–19. Displaying this information will promote transparency on the impacts of the PHE due to COVID–19, and we will appropriately caveat the data in order to mitigate potential public confusion.

Comment: A few commenters expressed support for our proposal to provide confidential performance feedback to hospitals on suppressed measures.

Response: We thank the commenters for their support. We will provide confidential feedback reports to hospitals for the pneumonia readmission measure, with the current specifications. In these confidential reports, hospitals will be able to see which of their patients were readmitted to the hospital, and which of their patients were excluded from the measure denominators to inform hospital quality improvement initiatives.

After consideration of the public comments we received, we are finalizing our proposal to suppress the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for FY 2023 as proposed, without modification.

c. Technical Measure Specification Update To Exclude COVID–19 Diagnosed Patients From All Other Condition/Procedure-Specific Readmission Measures Beginning With FY 2023

In the FY 2015 IPPS/LTCH final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital Readmissions Reduction Program (79 FR 50039). We reiterated this policy in the FY 2020 IPPS/LTCH final rule, stating our continued belief that the subregulatory process is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted (84 FR 42385). In the FY 2022 PPS/LTCH PPS proposed rule, we stated that due to the impact of the COVID–19 PHE on the measures used in the Hospital Readmissions Reduction Program, as described previously, we would be updating these five condition/procedure-specific readmission measures to exclude COVID–19 diagnosed patients from the measure denominators (86 FR 25464). We also stated this technical update would modify these five condition/procedure-specific readmission measures to exclude certain ICD–10 Codes that represented patients with a secondary diagnosis of COVID–19 from the measure denominators, but would retain the measures in the program. Although in the proposed rule we stated that the technical update would modify the condition/procedure-specific readmission measures to exclude patients with a secondary diagnosis of COVID–19 (86 FR 25462), it is possible that certain procedure-specific readmission measures could include patients with a primary diagnosis of COVID–19 in the measure cohort as well. Therefore, we are updating our language in this final rule to reflect that the technical measure specification updates would exclude patients with primary or secondary COVID–19 diagnoses.

We believe that excluding COVID–19 patients from the measure denominator will ensure that these five condition/procedure-specific readmission measures continue to account for readmissions as intended and meet the goals of the Hospital Readmissions Reduction Program. Additional resources about the current measure technical specifications and methodology for the Hospital Technical specification of the current readmission measures are provided at our website in the Measure Methodology Reports (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*). Hospital Readmissions Reduction Program resources are located at the Resources web page of the QualityNet website (available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995*).

We received public comments on this technical measure specification update. The comments we received and our responses are set forth in this section of this rule.

Comment: Many commenters expressed support for our technical measure specification updates removing COVID–19 patients from the denominator for the five remaining condition/procedure-specific readmission measures beginning in FY 2023. These commenters agreed that the COVID–19 public health emergency had a direct impact on the readmission measures as well as an indirect effect through complications and exacerbation of existing conditions. Several commenters noted that these technical updates to measure specifications

would help to mitigate the impact of the COVID–19 PHE on condition/procedure-specific readmission measures. A few commenters noted the importance of keeping the measures in the program, while also accounting for the impact of COVID–19 patients on measure cohorts.

Response: We thank the commenters for their support.

Comment: Several commenters supported the technical specification updates to remove COVID–19 patients from the measure denominators, but also encouraged CMS to continue analyzing COVID–19's impact on quality measures. These commenters added that impacts on measure performance may stem from more than just COVID–19 diagnoses, such as closing of long-term care facilities, lack of visitors to understand aftercare instructions, and lower elective procedure rates.

Response: We understand that the COVID–19 PHE is ongoing and may be impacting many aspects of the healthcare system and patient outcomes. We will continue to monitor the claims data that form the basis for these measure calculations to evaluate the effect of COVID–19 on quality measurement and to determine appropriate policies in the future.

Comment: Several commenters expressed concern that the technical measure specification updates to exclude COVID–19 patients from the five condition/procedure-specific readmission measures may not adequately address the impacts of COVID–19 on those measures. Several commenters also sought clarification on whether the exclusion would apply to patients who contract COVID–19 between the index admission and readmission. A few commenters questioned CMS to specify the ICD–10 codes that will be used to identify secondary diagnosis of COVID–19. A few commenters recommended additional exclusions to the measure specifications in order to account for those readmissions to ensure that CMS is not penalizing hospitals for readmissions due to COVID–19.

Response: We thank the commenters for their feedback. We share commenters' concerns regarding whether the exclusions discussed in the proposed rule adequately capture all COVID–19 readmissions. Therefore, we wish to clarify that we plan to remove any patients diagnosed with COVID–19, including a primary or secondary diagnosis of COVID–19, from both index admissions and readmissions in order to exclude from the measure cohort patients who are readmitted due to COVID–19 within the 30-day readmission period. We would like to clarify that we will be removing index admissions (from the denominator) that have a principal or secondary diagnosis present on admission (POA), of COVID–19 using the COVID–19 specific ICD–10 code (U07.1). We are explicitly noting the exclusion of principal diagnoses given the possible, though likely rare, scenario in which a patient is admitted for a CABG or THA/TKA procedure with a principal diagnosis of COVID–19. We will continue to monitor the claims data and COVID–19 coding practices. Additionally, we will be removing from the numerator any readmissions within 30 days that have a principal or secondary diagnosis POA, of COVID–19 (U07.1).

Comment: A few commenters expressed concern that the exclusions may not adequately adjust for the impacts of COVID–19 on the condition/procedure-specific readmission measures and recommended that CMS consider additional suppression policies, noting that the COVID–19 PHE impacted measure data for a variety of reasons, including higher patient acuity, disruptions in care due to the COVID–19 PHE, as well as challenges with available resources. A few commenters requested that CMS consider the impact of the COVID–19 PHE and exclusion of COVID–19 patients by modeling the potential impacts on hospital performance scores prior to finalizing these technical measure specification updates. A few commenters expressed concern that operational changes and fluctuations in volume may have unintended consequences on the calculation of performance scores.

Response: We appreciate commenters' concerns that the exclusions may not capture the totality of the impacts of the COVID–19 PHE on condition/procedure-specific readmission measures, and will continue to evaluate data collected during the COVID–19 PHE to assess whether additional measure suppressions or further exclusions may be necessary. We have based our measurement and program changes announced in this final rule based upon analyses of the most recently available data. As additional months of data become available, we will continue to conduct analyses to understand the evolving circumstances of the COVID–19 pandemic to inform future measurement approaches.

Comment: A few commenters recommended that CMS provide confidential feedback reports to hospitals that include the entire measure cohort for each condition/procedure-specific readmission measure, including COVID–19 patients, in order to help hospitals and clinicians better understand the relationship between COVID–19 and patient outcomes for these condition/procedure-specific readmission measures.

Response: We thank the commenters for their feedback, and will evaluate the feasibility of providing confidential feedback reports to hospitals that include condition/procedure-specific readmission measure data for patients with and without COVID–19 diagnoses. In these confidential reports, hospitals would be able to see which of their patients were excluded from the measures due to a qualifying COVID–19 diagnosis to inform hospital quality improvement initiatives.

Comment: A few commenters recommended that CMS continue to analyze COVID–19 PHE data to determine whether the technical measure specification updates should be extended beyond FY 2023 due to the continuing impact of COVID–19 on the condition/procedure-specific readmission measures.

Response: We thank the commenters for their feedback. We agree with commenters that it is important to continue monitoring the PHE's ongoing effects on condition/procedure-specific readmission measures, as this will inform our considerations about whether to extend the exclusions beyond FY 2023.

Comment: A few commenters expressed concern that removing patients with COVID–19 from the readmission measures would not adequately account for the effects of the PHE on the readmission measures, including for patients who did not contract COVID–19. These commenters requested that CMS consider suppression of the five readmission measures as the COVID–19 pandemic impacted hospital volume and operations.

Response: Our analyses of available data to date have estimated only minimal impacts of COVID–19 on readmission measure results (for measures other than pneumonia readmission) for the FY 2023 program year. The proportion of admissions and readmissions with a principal or secondary diagnosis of COVID–19 were very small due to the cohort definitions and affected performance period.

After consideration of the public comments we received, we are clarifying our technical measure specification update to remove any patients diagnosed with COVID–19, including a primary or secondary diagnosis POA of COVID–19, from both

index admissions and readmissions from the measure cohorts for these five condition/procedure-specific readmission measures.

7. Automatic Adoption of Applicable Periods for FY 2023 and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53375) for discussion of our previously finalized policy for defining ''applicable period''. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41434 through 41435) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42387), we finalized the ''applicable period'' consistent with the definition specified at 42 CFR 412.152, to calculate the readmission payment adjustment factor for FY 2022 as the 3-year time period of July 1, 2017 through June 30, 2020.[768]

The ''applicable period'' is the 3-year period from which data are being collected in order to calculate excess readmission ratios (ERRs) and payment adjustment factors for the fiscal year; this includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment. The ''applicable period'' for dually eligible beneficiaries is the same as the ''applicable period'' that we otherwise adopt for purposes of the Hospital Readmissions Reduction Program.

In order to provide greater certainty around future applicable periods for the Hospital Readmissions Reduction Program, in the FY 2021 IPPS/LTCH final rule (85 FR 58846), we finalized the automatic adoption of applicable periods for FY 2023 and all subsequent program years for the Hospital Readmissions Reduction Program. Beginning in FY 2023, the applicable period for the Hospital Readmissions Reduction Program will be the 3-year period beginning 1 year advanced from the previous program fiscal year's start of the applicable period. Under this policy, for all subsequent years, we will advance this 3-year period by 1 year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. Similarly, the applicable period for dual eligibility will continue to correspond to the applicable period for the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58845 through 58846) for a more detailed discussion of this topic. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25464), we did not propose any updates to this policy.

8. Identification of Aggregate Payments for Each Condition/Procedure and All Discharges for FY 2022

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for each condition/procedure using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For the FY 2022 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of specific ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure, because diagnoses and procedure codes for discharges occurring on or after October 1, 2015 (FY 2016) began reporting under the ICD–10–CM and ICD–10–PCS code sets as opposed to the previous ICD–9–CM code set.

We identify Medicare fee-for-service (FFS) claims that meet the criteria as previously described for each applicable condition/procedure to calculate the aggregate payments for excess readmissions. This means that claims paid for under Medicare Part C (Medicare Advantage) are not included in this calculation. This policy is consistent with the methodology to calculate ERRs based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2022, we proposed to continue to exclude admissions for patients enrolled in Medicare Advantage (MA), as identified in the Medicare Enrollment Database.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25464 through 25465), for FY 2022, we proposed to determine aggregate payments for excess readmissions, and aggregate payments for all discharges using data from MedPAR claims with discharge dates that align with the FY 2022 applicable period.[769] As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38232), we would determine the neutrality modifier using the most recently available full year of MedPAR data. However, we noted that, for the purpose of modeling the estimated FY 2022 readmissions payment adjustment factors for this final rule, we would use the proportion of dually eligible beneficiaries, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2022 Hospital Readmissions Reduction Program applicable period (July 1, 2017 through December 1, 2019).[770] For the FY 2022 program year, applicable hospitals will have the opportunity to review and correct calculations based on the FY 2022 applicable period of July 1, 2017 to December 1, 2019, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate that this period is intended to review the program calculations, and not the underlying data. For more information on the review and corrections process, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

In the proposed rule, we also proposed to continue to use MedPAR data corresponding to the applicable period for identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions for the Hospital Readmissions Reduction Program. We proposed to use the update of the MedPAR file for each Federal FY, which is updated 6 months after the end of each Federal FY within the applicable period, as our data source.

We welcomed public comment on this proposal to identify aggregate payments for each condition/procedure

[768] Although the FY 2022 applicable period is July 1, 2017 through June 30, 2020, we note that first and second quarter data from CY 2020 is excluded from consideration for program calculation purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE.

[769] Although the FY 2022 applicable period is July 1, 2017 through June 30, 2020, we note that first and second quarter data from CY 2020 is excluded from consideration for scoring purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating DRG payments would be adjusted to July 1, 2017 through December 1, 2019. Further information will be found in the FY 2022 Hospital Specific Report (HSR) User Guide located on QualityNet website at: *https://qualitynet.cms.gov/inpatient/hrrp/reports* that is anticipated to become available in August 2021.

[770] We note that in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25465), we used data from the FY 2021 Hospital Readmissions Reduction Program applicable period to estimate payment adjustment factors. We are updating these estimates in this final rule with data from the FY 2022 applicable period.

and all discharges for the FY 2022 applicable period using corresponding MedPAR data. The comments we received and our responses are set forth in this section of this rule.

Comment: A few commenters expressed support for our proposal to determine aggregate payments for excess readmissions, and aggregate payments for all discharges using data from MedPAR claims with discharge dates that align with the FY 2022 applicable period.

Response: We thank these commenters for their support.

Comment: A few commenters expressed support for the use of MedPAR data based on the FY 2022 applicable period of July 1, 2017 through December 1, 2019, which was modified due to the nationwide ECE granted in response to the COVID–19 PHE.

Response: We thank these commenters for their support.

After consideration of the public comments we received, we are finalizing our policy to identify aggregate payments for each condition/procedure and all discharges for the FY 2022 applicable period using corresponding MedPAR data as proposed, without modification.

9. Automatic Adoption of the Use of MedPAR Data Corresponding to the Applicable Period Beginning in FY 2023

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387 through 53390) for discussion of our previously finalized policy for the use of MedPAR claims data as our data source for determining aggregate payments for each condition/procedure and aggregate payments for all discharges during applicable periods. Most recently, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58846), we finalized our policy on the continued use of the MedPAR data corresponding to the applicable period for the Hospital Readmissions Reduction Program calculations for the FY 2021 applicable period. We also finalized our policy to use the update of the MedPAR file for each Federal FY, which is updated 6 months after the end of each Federal FY within the applicable period, as our data source to identify discharges within the FY 2021 applicable period during that fiscal year. Similarly, in section V.G.8 of this final rule, we are finalizing our proposal to use MedPAR data corresponding to the applicable period for the Hospital Readmissions Reduction Program calculations for the FY 2022 applicable period, and to use the update of the MedPAR file for each Federal FY, which is updated 6 months after the end of each Federal FY within the applicable period, as our data source.

We continue to believe that the use of MedPAR claims data is the appropriate source for identifying aggregate payments for each condition/procedure and all discharges during the corresponding applicable period for the Hospital Readmissions Reduction Program. In order to provide greater certainty around future applicable periods for the Hospital Readmissions Reduction Program, in the FY 2021 IPPS/LTCH final rule (85 FR 58845 through 58846), we finalized the automatic adoption of applicable periods for FY 2023 and all subsequent program years for the Hospital Readmissions Reduction Program. Under this policy, the 3-year applicable period will automatically advance by 1 year beginning in FY 2023. Because the MedPAR data used for the Hospital Readmissions Reduction Program calculations corresponds to the applicable period, we believe that the automatic adoption of the use of MedPAR data corresponding to the applicable period for Hospital Readmissions Reduction Program calculations each year will similarly streamline the process and provide additional clarity and consistency to the program.

Therefore, in the FY 2022 IPPS/LTCH proposed rule (86 FR 25465), we proposed to automatically adopt the use of MedPAR data corresponding to the applicable period for Hospital Readmissions Reduction Program calculations for FY 2023 and all subsequent program years. We proposed that, beginning in FY 2023, the MedPAR data used to calculate aggregate payments for each condition/procedure and for all discharges will be the 3-year period beginning 1 year advanced from the previous program fiscal year's MedPAR data corresponding to the applicable period for Hospital Readmissions Reduction Program calculations. Under this proposal, for all subsequent years, we would advance this 3-year period by 1 year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. We also proposed to automatically adopt the use of the update of the MedPAR file for each Federal FY, which is updated 6 months after the end of each Federal FY within the applicable period, as our data source, and to similarly advance this by 1 year from the previous program fiscal year.

We welcomed public comment on this proposal. The comment we received and our response are set forth in this section of this rule.

Comment: A commenter expressed support for the proposal to automatically adopt the use of MedPAR data to its corresponding applicable period beginning in FY 2023 program year and all subsequent program years.

Response: We thank the commenter for its support.

After consideration of the public comment we received, we are finalizing our policy to automatically adopt the use of MedPAR data corresponding to the applicable period for Hospital Readmissions Reduction Program calculations for FY 2023 and all subsequent program years as proposed, without modification.

10. Calculation of Payment Adjustment Factors for FY 2022

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups, based on the proportion of dually eligible beneficiaries served by each hospital, in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019. Section 1886(q)(3)(D) also states that this methodology could be replaced through the application of subclause (E)(i), which states that the Secretary may take into account the studies conducted and the recommendations made by the reports required by section 2(d)(1) of the IMPACT Act of 2014 (Pub. L. 113–185; 42 U.S.C. 1395 note) with respect to risk adjustment methodologies. On June 29, 2020,[771] the second Report to Congress by the Department's Office of the Assistant Secretary for Planning and Evaluation (ASPE) on social risk and Medicare's value-based purchasing programs came out. We are continuing our review of these recommendations and will address them as appropriate in future rulemaking.

We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the payment adjustment methodology. We did not propose any changes to this payment adjustment calculation methodology for FY 2022 in the proposed rule (86 FR 25466).

[771] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program.'' March 2020. Available at: *https://aspe.hhs.gov/system/files/pdf/263676/Second-IMPACT-SES-Report-to-Congress.pdf*.

11. Calculation of Payment Adjustment for FY 2022

Section 1886(q)(3)(A) of the Act defines the payment adjustment factor for an applicable hospital for a fiscal year as ''equal to the greater of: (i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).'' Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of aggregate payments for excess readmissions to aggregate payments for all discharges, scaled by the neutrality modifier. The calculation of this ratio is codified at 42 CFR 412.154(c)(1) and the floor adjustment factor is codified at 42 CFR 412.154(c)(2). Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified in our regulations at 42 CFR 412.154(c)(2), for FY 2022, the payment adjustment factor will be either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2022, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

For additional information on the FY 2022 payment calculation, we refer readers to the Hospital Readmissions Reduction Program information and resources available on our QualityNet website. We did not propose any changes to our calculation of payment methodology in the proposed rule (86 FR 25466).

12. Overall Hospital Quality Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Ratings (Overall Star Ratings). The Overall Star Ratings utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital Readmissions Reduction Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule for details (85 FR 86193 through 86236). We did not propose any changes to our calculation of the Overall Star Ratings.

13. Extraordinary Circumstance Exception (ECE) Policy for the Hospital Readmissions Reduction Program

a. Background

(1) Previously Established Extraordinary Circumstance Exception (ECE) Policy Under the Hospital Readmissions Reduction Program

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38239 through 38240) for discussion of our Extraordinary Circumstances Exception (ECE) policy. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543), we adopted an ECE policy for the Hospital Readmissions Reduction Program, which recognized that there may be periods of time during which a hospital is not able to submit data (from which readmission measures data are derived) in an accurate or timely fashion due to an extraordinary circumstance beyond its control. When adopting this policy, we noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's excess readmission ratios for the applicable performance period. By minimizing the data excluded from the program, the policy enabled affected hospitals to continue to participate in the Hospital Readmissions Reduction Program for a given fiscal year if they otherwise continued to meet applicable measure minimum threshold requirements. We expressed the belief that this approach would help alleviate the burden for a hospital that might be adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the Hospital Readmissions Reduction Program. We further observed that section 1886(q)(5)(D) of the Act permits the Secretary to determine the applicable period for readmissions data collection, and we interpreted the statute to allow us to determine that the period not include times when hospitals may encounter extraordinary circumstances. This policy was similar to the ECE policy for the Hospital Inpatient Quality Reporting (IQR) Program, as initially adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651) and modified in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277). We also considered how best to align an extraordinary circumstance exception policy for the Hospital Readmissions Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital Value-Based Purchasing (VBP) Program, to the extent feasible.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38239), we modified the requirements for the Hospital Readmissions Reduction Program ECE policy to further align with the processes used by other quality reporting and VBP programs for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control.

(2) Extraordinary Circumstance Exception (ECE) Granted in Response to the COVID–19 Public Health Emergency

On March 22, 2020, in response to COVID–19, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs.[772] Specifically, we announced that we were excluding data for the first and second quarters of CY 2020. On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare quality reporting and VBP program.[773] For the Hospital Readmissions Reduction Program, we stated that qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the readmission measures.

(3) Updated Application of the ECE Granted in Response to COVID–19

On September 2, 2020, we published the Interim Final Rule with comment period (IFC), ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19

[772] CMS, Press Release, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19 (Mar. 22, 2020), *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[773] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

Public Health Emergency'' (85 FR 54820). The IFC updated the ECE we granted in response to the PHE for COVID–19, for the Hospital Readmissions Reduction Program and several other quality reporting programs (85 FR 54827 through 54838).

In the IFC, we updated the previously announced application of our ECE policy for the Hospital Readmissions Reduction Program (85 FR 54832 through 54833) to the COVID–19 PHE to exclude any data submitted regarding care provided during the first and second quarters of CY 2020 from our calculation of performance for FY 2022, FY 2023, and FY 2024. We expressed concern that excess readmission ratios calculated using excepted claims data could affect the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19, and therefore may not provide a nationally comparable assessment of performance in keeping with the program goal of national comparison.

In the IFC, we welcomed public comments on our policy to exclude any data submitted regarding care provided during first and second quarter of CY 2020 from our calculation of performance for FY 2022, FY 2023, and FY 2024. We are responding to those public comments in this FY 2022 IPPS/LTCH PPS final rule.

In the September 2, 2020 IFC, we also announced that if, due to ECEs related to the COVID–19 PHE, we do not have enough data to reliably measure national performance, we may propose to not assess hospitals based on such limited data or make temporary payment adjustments to facilities under the Hospital Readmissions Reduction Program for the affected program year. We stated that, if circumstances warranted, we could propose to suspend prospective application of program penalties or payment adjustments through the annual IPPS/LTCH PPS proposed rule. We also stated that, in the interest of time and transparency, we would provide subregulatory advance notice of our intentions to suspend such penalties and adjustments through routine communication channels to facilities, vendors, and QIOs. The communications could include memos, emails, and notices on the public QualityNet website (*https://www.qualitynet.cms.gov/*).[774]

We received public comments on our policy to exclude any data submitted regarding care provided during first and second quarter of CY 2020 from our calculation of performance for FY 2022, FY 2023, and FY 2024. The comments we received and our responses are set forth in this section of this rule.

Comment: Several commenters supported CMS' updated application of the ECE granted in response to the PHE due to COVID–19. A few commenters also agreed with CMS' concerns regarding the national comparability of data from Q1 and Q2 of CY 2020 and noted that the integrity and validity of any measurement calculations associated with these data could be compromised. A commenter encouraged CMS to continue accepting data for purposes of evaluating the impact of COVID–19 on hospitals' outcomes.

Response: We thank commenters for their support.

Comment: A commenter encouraged CMS to consider excluding the remainder of CY 2020 data from use in payment determinations.

Response: We thank the commenter for this feedback. Although we are not expanding the ECE we granted in response to the COVID–19 to exclude data for the remainder of CY 2020 data from use in the Hospital Readmissions Reduction Program, we refer readers to sections V.G.5 and V.G.6 for further discussion of policies that we are adopting in response to the impact of the COVID–19 PHE on measure data used in payment determinations.

Comment: A commenter recommended that CMS consider factors which may impact hospital performance in the Hospital Readmissions Reduction Program besides the quantity of data submitted in deciding whether or not to assess hospitals, expressing concern regarding the reliability of the data that would be used to measure national performance. The commenter recommended that CMS should not impose penalties under the Hospital Readmissions Reduction Program for the affected program year.

Response: We thank commenter for this feedback. We refer readers to our measure suppression policy in V.G.5, in which we consider factors which may impact the reliability and comparability of the measure data used to assess hospital performance in the Hospital Readmissions Reduction Program due to the COVID–19 PHE. Under this policy, we are suppressing the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for FY 2023 due to the potential impact of COVID–19 diagnoses on the reliability of the data that would be used to measure national performance on that measure. We are also updating the technical specifications for the remaining five condition/procedure-specific measures to exclude COVID–19 diagnoses from the measure cohorts to address the potential impact of COVID–19 on measure data quality. We note that due to our policy to exclude any data submitted regarding care provided during first and second quarter of CY 2020, the FY 2022 applicable period for the Hospital Readmissions Reduction Program will not include measure data impacted by the COVID–19 PHE.

As established in the September 2020 IFC, we have finalized our updated application of the ECE granted in response to the COVID–19 PHE.

b. General Clarifications to Hospital Readmissions Reduction Program ECE Policy

After the nationwide ECE granted in response to the COVID–19 PHE ended, we received several requests from hospitals for individual ECEs under the Hospital Readmissions Reduction Program, due to extraordinary circumstances resulting from the continuing impact of the PHE. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25467 through 25468), we clarified our ECE policy to highlight that an ECE granted under the Hospital Readmissions Reduction Program would exclude claims data during the corresponding ECE period. Although we have considered the feasibility and implications of excluding data under the ECE policy for the Hospital Readmissions Reduction Program, we have never specified the types of data that would be excluded under an ECE granted to an individual hospital. Considering that the Hospital Readmissions Reduction Program only uses claims data, we would like to clarify our ECE policy to specify that claims data will be excluded from calculations of measure performance under an approved ECE for the Hospital Readmissions Reduction Program.

The FY 2016 IPPS/LTCH final rule specifies that we may waive reporting requirements for the Hospital Readmissions Reduction Program in response to ECE requests, in alignment with the Hospital Inpatient Quality Reporting (IQR) policy (80 FR 49542). Although the Hospital Readmissions Reduction Program and the Hospital IQR Program use different sources of data and have different requirements

[774] We note that the QualityNet website (previously at *QualityNet.org*) has transitioned to a *QualityNet.cms.gov*.

depending on the type of measure, the ECE policy applies to both programs. Therefore, in the FY 2022 IPPS/LTCH proposed rule, we clarified that although an approved ECE for the Hospital Readmissions Reduction Program would exclude excepted data from Hospital Readmissions Reduction Program payment reduction calculations, we did not propose to waive the data submission requirements of a hospital for claims data (86 FR 25467). For example, for claims data, we require a hospital to submit claims to receive payments for the services they provided to patients. Although an individual ECE approval under the Hospital Readmissions Reduction Program would except data submitted by a hospital from Hospital Readmissions Reduction Program calculations, a hospital would still need to submit its claims in order to receive payment outside the scope of the Hospital Readmissions Reduction Program for services provided.

We have also received a few requests from hospitals for ECEs under the Hospital Readmissions Reduction Program, in which the hospitals requested an exception from the Hospital Readmissions Reduction Program payment reduction. The ECE policy for the Hospital Readmissions Reduction Program is intended to provide relief for a hospital that has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the hospital's control by excepting data from the period during which performance was impacted. The hospital would still be evaluated for the remainder of the applicable period during which performance was not impacted. The ECE policy is not intended to extend to payment reductions. Therefore, we clarify that, although an approved ECE for the Hospital Readmissions Reduction Program would exclude excepted data from Hospital Readmissions Reduction Program payment reduction calculations, it does not exempt hospitals from payment reductions under the Hospital Readmissions Reduction Program. Instead of relying upon our ECE policy, we are relying upon our authority under subsection 1886(q)(5)(A)(i) of the Act to determine the scope of ''applicable conditions'', including the Secretary's authority to utilize his own criteria to select measures to be used to calculate the excess readmission measure.

c. Clarification of the Impact of ECE Excluded Data for the Hospital Readmissions Reduction Program

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25468), we clarified the impact of data which had been excluded from the Hospital Readmissions Reduction Program due to the nationwide ECE that was granted in response to COVID–19 on upcoming Hospital Readmissions Reduction Program calculations. In order to determine and evaluate what kind of impact the nationwide ECE might have on the Hospital Readmissions Reduction Program, we conducted analyses to simulate the impact of an altered performance period on program eligibility and the resulting payment impacts to hospitals using pre-COVID–19 data from the FY 2020 Hospital Readmissions Reduction Program year. This analysis was intended to evaluate what patterns we might observe in Hospital Readmissions Reduction Program eligibility and payment as a result of excluding 6 months of data due to the ECE granted in response to the PHE for COVID–19. Our analysis found that there would be a minimal impact on hospitals if 6 months of data were removed from Hospital Readmissions Reduction Program calculations. We are performing additional analyses as CY 2020 data becomes available, and we will provide updated analyses as necessary when it becomes available.

Although the FY 2022 applicable period is July 1, 2017 through June 30, 2020, due to the first and second quarter CY 2020 claims exception period and the 30-day window to identify readmissions, the period for calculating ERRs would be adjusted to July 1, 2017 through December 1, 2019. The period for calculating DRG payments would similarly be adjusted to July 1, 2017 through December 1, 2019 to align with the period to calculate ERRs. We would also note that CY 2019 data would be used to calculate the Neutrality Modifier, as that would be the most recent full year of data (since Q1 and Q2 CY 2020 data are excluded from FY 2020 data under the nationwide ECE). Finally, we note that each of the readmission measures uses claims data for the 12 months prior to the index hospitalization as well as index hospitalization claims for risk adjustment (76 FR 51672). Due to the nationwide ECE that was granted in response to the COVID–19 PHE, the condition/procedure-specific measures will use less than 12 months of data for risk adjustment for admissions between July 1, 2020 and June 30, 2021 during the FY 2023 applicable period. For example, if not for the COVID–19 PHE and subsequent nationwide ECE, an admission on July 1, 2020 would have included 12 months of prior claims data—a lookback period of July 2, 2019 through June 30, 2020—for risk adjustment. Because claims data from January 1, 2020 through June 30, 2020 are excluded under the nationwide ECE, an admission on July 1, 2020 will have a shorter lookback period of July 2, 2019 through December 31, 2019. Comorbidities from the index admission will continue to be used for all admissions.

In the FY 2020 IPPS/LTCH PPS final rule, we finalized our policy to adopt a subregulatory process to make nonsubstantive updates to payment adjustment factor components to facilitate the program's operation when minor changes are required, but do not substantively impact the program's previously finalized policies (84 FR 42385 through 42387). Although these changes are substantive, they do not substantially impact the outcomes in comparison to the Hospital Readmissions Reduction Program's previously finalized policies. Implementation of this temporary policy will be addressed through the subregulatory process. For more details on these subregulatory updates, we refer readers to the Hospital Specific Report (HSR) User Guide located on QualityNet website at: *https://qualitynet.cms.gov/inpatient/hrrp/reports*.

14. Request for Public Comment on Possible Future Stratification of Results by Race and Ethnicity for Condition/Procedure-Specific Readmission Measures

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[775] As described in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25554 through 25561), in response to statute and policy reports from the Assistant Secretary for Planning and Evaluation (ASPE) of HHS and the National Academies of Science, Engineering and Medicine to better account for social risk factors in the Medicare program,[776] we have created

[775] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[776] ASPE, Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs (2016), *https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf*. For

two complementary methods to calculate disparities in condition/procedure-specific readmission measures (the CMS Disparity Methods). The first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of those differences, or disparities, across hospitals, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) is complementary and assesses hospitals' outcome rates for subgroups of patients across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. We refer readers to the technical report describing the CMS Disparity Methods in detail as well as the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the posted Disparity Methods Updates and Specifications Report posted on the QualityNet website. The CMS Disparity Methods have thus far focused on dual eligibility, a proxy for social risk factors, as the main stratification variable for reporting disparity results. These stratified data are provided in confidential Hospital Specific Reports (HSRs) for six condition/procedure-specific readmission measures and not publicly reported at this time. The disparity methods were designed to accommodate additional types of stratification variables, such as race and ethnicity, language preference, and disability status.

As described in the proposed rule (86 FR 25557 through 25560), we sought comment on potentially expanding our methods for stratified reporting of the Disparity Methods to better illuminate social disparities in populations served by Medicare-participating hospitals. As described in the proposed rule, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and procedural complications. We are, in particular, exploring the significance of racial and ethnic inequities, as well as other social factors such as language preference and disability status, in outcomes in the Hospital Readmissions Reduction Program.[777] Expanding the disparity methods to include stratified results by both dual eligibility and race and ethnicity, as well as language preference and disability status, may enable a more comprehensive assessment of health equity and support initiatives to close the equity gap. We believe that hospitals will be able to use the results from the disparity methods to identify and develop strategies to promote health equity.

More specifically, we sought comment on expanding our efforts to provide hospital-level results of both the Within- and Across-Hospital Disparity Methods, as described in the proposed rule (86 FR 25557 through 25560), using indirectly estimated race and ethnicity, as well as additional social factors, such as language preference and disability status. Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[778] Imputed data are most commonly used at the population level, where aggregated results form a more accurate description of the population than existing, imperfect data sets. The proposed rule also summarized the existing challenges in accurately determining race and ethnicity in our administrative data, the need for using advanced statistical methods for indirectly estimating race and ethnicity, and the previous algorithms developed to indirectly estimate race and ethnicity in our data. The expanded methods would be reported at the hospital-level, and provided to hospitals in confidential HSRs for six condition/procedure-specific readmission measures, stratified by both dual eligibility and race/ethnicity: (1) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505); (2) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515); (3) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891); (4) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization (NQF #0330); (5) Hospital-Level 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551); and (6) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506), for groups where results are technically feasible, adequately representative, and statistically reliable.[779]

To allow stakeholders an opportunity to become more familiar with, and gain comfort in interpreting stratified results using indirect estimation of race and ethnicity as described in the proposed rule, hospitals would receive *confidential HSRs* containing results for the six condition/procedure-specific readmission measures, stratified by both dual eligibility and race/ethnicity in Spring 2022, prior to anticipated future publication of results in Spring 2023. Any proposal to publicly display stratified quality measure data for these six condition/procedure-specific readmission measures as previously described on the Care Compare website, or expand stratified reporting to additional social risk factors, would be made through future rulemaking.

We invited public comment on the following: (1) The possibility of confidentially reporting in HSRs stratified results using indirectly estimated race and ethnicity in addition to the currently reported results stratified using dual eligibility, for the six condition/procedure-specific readmission measures, and by expansion of standardized data collection to additional social factors, such as language preference and disability status; (2) the possibility of publicly reporting stratified results using both indirectly estimated race and ethnicity, and dual eligibility, publicly on Care Compare, after at least one year of confidential reporting and further rulemaking, for the six condition/procedure-specific measures; and (3) possible mechanisms of incorporating other demographic characteristics into analysis that address and advance

more information, see National Academies of Sciences, Engineering, and Medicine, Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors (2016), *https://doi.org/10.17226/21858*. See also, Improving Medicare Post-Acute Care Transformation Act of 2014 (2014), *https://www.govinfo.gov/content/pkg/BILLS-113hr4994enr/pdf/BILLS-113hr4994enr.pdf*.

[777] For example, see the RIT Race Code, available at *https://www.resdac.org/cms-data/variables/research-triangle-institute-rti-race-code*. See also, Health Serv Res. 2019 Feb; 54(1):13–23. doi: 10.1111/1475–6773.13099. Epub 2018 Dec 3.

[778] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[779] Although we proposed to suppress the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) in section V.G.6 of the proposed rule, we note that the measure is not being proposed for removal and is therefore still considered one of the six condition/procedure-specific readmission measures included in the Hospital Readmissions Reduction Program.

health equity, such as the potential to include administrative and self-reported data to measure co-occurring disability status.

Comment: Several commenters supported the creation and dissemination of measures stratified by dual eligibility status, imputed race/ethnicity, and other demographic and social risk factors. Some commenters explicitly supported stratification by imputed race and ethnicity for readmission measures. A commenter noted imputed race could be used as a way to expand the collection of additional social risk factors. Others noted that publicly reporting stratified results could build trust and transparency with patients and communities; help understand potential patterns in access and outcomes for patients with social risk factors; identify patient populations that would benefit from quality improvement strategies; and develop quality improvement strategies targeted to specific populations.

Response: We thank the commenters for their feedback. We also anticipate that stratified hospital-level reporting by dual eligibility status, indirectly estimated race/ethnicity, and other demographic and social factors, even if confidential, has the potential to support quality improvement activities to improve quality of care and reduce disparities in hospital outcomes. We intend to begin confidential reporting of the six condition-specific readmission measures using both dual eligibility and indirect estimation of race and ethnicity. We will continue to evaluate the validity of the readmission measures stratified by indirect estimation during the confidential reporting period. We plan to report results confidentially to hospitals in Spring 2022 where results are technically feasible, meaningful, and statistically reliable. Any potential future proposal to publicly display the disparity results on Care Compare would be made through future rulemaking.

Comment: Several other commenters that supported public reporting of stratified results shared some concerns and suggestions for how to report the data. Several commenters stated that stratified results should only be publicly available for dual eligibility and self-reported race and ethnicity. Some commenters were concerned about using imputed data for stratification by race and ethnicity and explained that reporting this information publicly could have unintended consequences such as confusion for consumers and the public. Some commenters recommended using indirect methods of calculating race and ethnicity for the purposes of stratifying measures for confidential reporting only. Many commenters noted concern about the lack of accuracy of imputed data. They recommended against using imputed data in programs that affect payment adjustments.

Response: We are sensitive to the concerns raised by stakeholders about indirect estimation. As we summarized in the proposed rule (86 FR 25558), the Medicare program does not directly collect information from beneficiaries on race and ethnicity, instead relying on data collected by the Social Security Administration. A number of barriers contribute to this information being insufficiently accurate to examine hospital-level disparities. For example, prior to 1980, only three categories (White, Black, and Other) were available for individuals to self-report race, and respondents were not able to indicate Asian, American Indian/Alaska Native, Hispanic, or Pacific Islander identities. As a result of these constrained response options, many current beneficiaries may not have had the opportunity to accurately self-report their race and ethnicity. Although we have undertaken significant efforts to update incorrect race and ethnicity information many inaccuracies remain limiting our ability to measure disparities.

As summarized in the proposed rule (86 FR 25558), in recent years we have sponsored the development of two indirect estimation algorithms, both intended to correct and improve administrative information on race and ethnicity. Indirect estimation methods such as these can generally be used in two different ways: (a) To estimate race/ethnicity in the absence of self-reported data; or (b) to improve administrative data in which beneficiaries provided a self-report of race/ethnicity but were not permitted a full set of response options (post-1980). While there is evidence supporting the validity of both approaches,[780] accuracy and performance is particularly high in situation (b), where indirect estimation allows the administrative variables to better match the responses people would give when permitted a full set of response options. The approach for indirect estimation we intend to apply is situation (b), which uses an algorithm to augment existing data to allow a constrained administrative self-reported variable to better match what Medicare beneficiaries themselves may have chosen when given a comprehensive set of response options on race and ethnicity.

The Medicare Bayesian Improved Surname Geocoding Version 2.1 (MBISG 2.1) uses the original beneficiary self-report, but uses additional information supplied by Medicare beneficiaries and information about neighborhood composition, to make this variable better match what Medicare beneficiaries themselves self-report when given a full set of response options. With respect to Asian and Pacific Islander, Black, Hispanic, and White Medicare beneficiaries, the improved version of the administrative variable has 96–99% concordance with what Medicare beneficiaries themselves report when allowed a full set of response options,[781] matching much better than the original self-reported variable in which most Medicare beneficiaries were not allowed to indicate Asian, American Indian/Alaska Native, Hispanic, or Pacific Islander identities. The MBISG 2.1 also offers distinct advantages because it generates probabilities of identification in each racial and ethnic group for each beneficiary.

The MBISG 2.1 incorporates multiple sources of information to develop racial and ethnic probabilities. In addition to the information on race and ethnicity which that person reported to the SSA, the model also considers the person's first and last name, the composition of the census block group where they live, and other demographic information that Medicare beneficiary shared. Through such a holistic approach, the MBISG 2.1 can make accurate comparisons between groups of Medicare beneficiaries regarding the quality of care received, including people whose surnames are common among several racial and ethnic groups, and people who changed their surnames upon marriage. The MBISG 2.1 is also designed to consider those who identify as Multiracial and allows measurement in Census categories that distinguish those who chose single or multiple racial identity, as well as considering endorsement of Hispanic ethnicity separately. Notably, we only intend to use the MBISG 2.1 to make inferences about aggregated groups at the hospital level, and do not intend to use it to make inferences about any single individual, validation studies indicate that these aggregate estimates

[780] Dembosky JW, Haviland AM, Haas A, Hambarsoomian K, Weech-Maldonado R, Wilson-Frederick SM, Gaillot S, Elliott MN. Indirect Estimation of Race/Ethnicity for Survey Respondents Who Do Not Report Race/Ethnicity. Med Care. 2019 May;57(5):e28–e33. doi: 10.1097/MLR.0000000000001011. PMID: 30520838. Available at: *https://pubmed.ncbi.nlm.nih.gov/30520838/*.

[781] Ibid.

further improve upon the higher predictive accuracy of the model.[782]

We believe that use of statistical imputation models, such as the MBISG 2.1 will permit us to provide more accurate, less biased information on disparities in hospital outcomes when reported confidentially. We plan to report results confidentially to hospitals in Spring 2022 where results are technically feasible, meaningful, and statistically reliable. Any potential future proposal to publicly display the disparity results on Care Compare would be made through future rulemaking. We are sensitive to the concerns raised by stakeholders and will continue to evaluate the validity of the readmission measures when stratified by indirect estimation during the confidential reporting period.

Comment: Some commenters shared concerns about data privacy and raised doubt about the actionability of indirectly estimating race and ethnicity data for stratified measures.

Response: We prioritize the privacy of the personal information of our beneficiaries and are sensitive to concerns raised by commenters about privacy and the use of data algorithms to infer potentially sensitive information about individuals. We are also sensitive to the need for hospitals to receive transparent information on health care quality measures, including the opportunity to review measure calculations and lists of potentially eligible patients. Notably, we only intend to use the MBISG 2.1 to make inferences about aggregated groups at the hospital level, and do not intend to use it to make inferences about any single individual, validation studies indicate that these aggregate estimates further improve upon the high predictive accuracy of the MBISG 2.1. At this time, we do not intend to share the individual-level race and ethnicity estimations or probabilities with hospitals during the confidential reporting period. We look forward to opportunities to address this issue with stakeholders in the future.

Comment: Several commenters raised concerns about the reliability of disparity results. Specifically, they noted that groups of 10 patients may be too small to produce reliable disparity estimates at the hospital level and highlighted the need to analyze the stability of the random effect model.

Response: We agree that achieving statistical reliability of measure results is important to provide more accurate, less biased information on disparities in hospital outcomes. We will apply the same reliability standards to reporting of disparities results as we do for other measures that are publicly or confidentially reported. For measures that rely on a random effect model we will assess model stability and random effect variance prior to deriving any results, and reporting thresholds will be adjusted based on model results.

Results will only be provided to hospitals where results are technically feasible, meaningful, and statistically reliable. Additional technical materials on minimum sample size thresholds will be posted on the QualityNet website.

Comment: Commenters suggested that new reporting mechanisms may be necessary. Several commenters suggested that public reporting should occur only after enough time has passed to allow for testing messaging, conducting focus groups, and other techniques to ensure public data are comprehensible. A commenter suggested including text to aid interpretation of publicly reported results. Others suggested public reporting should occur after several years of confidential reporting to ensure there is enough time to develop, test, and implement data review and correction mechanisms.

Response: We thank the commenters for their feedback. We are sensitive to the concerns raised by stakeholders about the need for enough time to allow for testing of the new methods prior to any future public reporting. As part of initial confidential reporting, we will provide information on the QualityNet website which aids users in interpretation of the methods and results during the confidential reporting period. Any potential future proposal to publicly display the disparity results on Care Compare would be made through future rulemaking with opportunity for additional public feedback.

Comment: A commenter shared a concern about comparing disparity results across all hospitals and recommended comparing results only across hospitals with similar patient populations and communities.

Response: We thank the commenter for their feedback. We will continue to evaluate the validity of the readmission measures stratified by indirect estimation, including examining for differences in hospital performance based on hospital characteristics and patient and community composition, during the confidential reporting period.

Comment: Several commenters noted the need to stratify results beyond dual eligibility and race/ethnicity to help hospitals close the equity gap. They supported the collection and use of additional equity-related predictor variables such as language, disability status, financial strain, housing status, LGBTQ status, and ''evidence-based social determinants''. A commenter recommended exploring methods to use additional demographic characteristics in analyses. Another commenter suggested that the Quality Reporting Document Architecture files would have the necessary information for Within- and Across-Hospital Disparity Methods their use would limit provider burden.

Response: We appreciate the feedback provided by the commenters regarding stratification by other demographic characteristics in order to further address and advance health equity. We agree with commenters that many variables impact health equity, and note that this request for public comment is just a first step in addressing the equity gap. We will investigate the suggested predictor variables for use in future reports in this program and across our programs. We agree that Quality Reporting Document Architecture files and use of Certified Electronic Health Record Technology would limit provider burden on any future data collection efforts for future consideration. We will continue to take all concerns, comments, and suggestions into account in future policies.

Comment: Several commenters supported standardizing data sources to capture social risk factors. A commenter highlighted that data used for stratification should be complete and accurate. Another commenter suggested that health information technology standards and guidance are needed to standardize data collection processes. Another commenter recommends that CMS should use existing data resources as a starting point for building a health equity framework instead of requiring hospitals to report additional data.

Response: We appreciate the feedback provided by the commenters regarding approaches for incorporating other demographic characteristics into analyses that address and advance health equity. When considering future policy development, we agree that CMS would conduct any future collection of demographic and social data in a manner that minimizes provider reporting burden. We will take commenters' feedback into consideration in future policy development.

[782] MBISG 2.1 validation results performed under contract #GS–10F–0012Y/HHSM–500–2016–00097G. Pending public release of the 2021 Part C and D Performance Data Stratified by Race, Ethnicity, and Gender Report, available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

Comment: Many commenters expressed overall support of CMS' goals to improve health care outcomes for Medicare beneficiaries and supported the stratification of measures in the Hospital Readmissions Reduction Program to identify and understand disparities. They noted that providing stratified measures could help hospitals identify gaps and advance equity but had concerns about the timeline and process of reporting the data. Some commenters recommended that if stratification is used to support disparity identification, then there should be clear statements around the intended use of the stratification variables. Several commenters also recommended updates to the Hospital Readmissions Reduction Program to better address health equity issues. For example, a commenter noted the need to risk adjust readmission measures by social risk factors, while another commenter suggested that the Hospital Readmissions Reduction Program should be streamlined into a more comprehensive program to better incorporate and address health equity.

Response: We appreciate the feedback provided by the commenters regarding measuring health equity in our hospital quality measurement programs, including the Hospital Readmissions Reduction Program. We will continue to take all concerns, comments, and suggestions into account in our future policies.

15. Regulatory Updates (42 CFR 412.154)

We proposed to update the references to CMS resources in regulation text (86 FR 25470). First, we note that we renamed our Hospital Compare website. It is now referred to as Care Compare and is available at: *https://www.medicare.gov/care-compare*. We proposed to revise our regulations for the Hospital Readmissions Reduction Program at 42 CFR 412.154(f)(4) to reflect the new website name. We proposed to amend CFR 412.154(f)(4), by adding the phrase ''or successor website'' so that the text reads ''Hospital Compare website or successor website.'' [783]

We invited public comment on our proposal. The comment we received and our response are set forth in this section of this rule.

Comment: A commenter expressed support for the update to the regulatory text that reflects the renaming of Hospital Compare to Care Compare.

Response: We thank this commenter for its support.

After consideration of the public comment we received, we are finalizing our proposal to update the regulatory text at 42 CFR 412.154(f)(4) as proposed, without modification.

H. Hospital Value-Based Purchasing (VBP) Program: Policy Changes

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to our codified requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.168.

1. Flexibilities for the Hospital VBP Program in Response to the Public Health Emergency (PHE) Due to COVID–19

a. Measure Suppression Policy for the Duration of the PHE for COVID–19

In previous rules, we have identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating hospitals' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 public health emergency (PHE), which has had, and continues to have, significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 pandemic and associated PHE has impeded effective quality measurement in many ways. Changes to clinical practices to accommodate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data used in quality measurement and the resulting quality scores. Measures used in the Hospital VBP Program need to be evaluated to determine whether their specifications need to be updated to account for new clinical guidelines, diagnosis or procedure codes, and medication changes that we have observed during the PHE. Additionally, because COVID–19 prevalence is not consistent across the country, hospitals located in different areas have been affected differently at different times throughout the pandemic. Under those circumstances, we remain significantly concerned that Hospital VBP Program quality measure scores that are calculated using data submitted during the PHE for COVID–19 are distorted and will result in skewed payment incentives and inequitable payments, particularly for hospitals that have treated more COVID–19 patients than others.

It is not our intention to penalize hospitals based on measure scores that we believe are distorted by the COVID–19 PHE and, thus, not reflective of the quality of care that the measures in the Hospital VBP Program were designed to assess. As previously discussed, the COVID–19 PHE has had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including those made on clinical topics covered by the Hospital VBP Program's measures. As a result of the COVID–19 PHE, hospitals could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, lower incentive payments in the Hospital VBP Program. We are also concerned that regional differences in COVID–19 prevalence during the performance periods for the FY 2022 and FY 2023 Hospital VBP Programs, which include CY 2020 data, have directly affected hospitals' measure scores for the FY 2022 and FY 2023 Hospital VBP program years. Although these regional differences in COVID–19 prevalence rates do not reflect differences in the quality of care furnished by hospitals, they directly affect the value-based incentive payments that these hospitals are eligible to receive and could result in an unfair and inequitable distribution of those incentives. These inequities could be especially pronounced for hospitals that have treated a large number of COVID–19 patients.

Therefore, we proposed to adopt a policy for the duration of the PHE for COVID–19 that would enable us to suppress the use of data for a number of measures if we determine that circumstances caused by the COVID–19 PHE have affected those measures and the resulting Total Performance Scores significantly (86 FR 25470). We also proposed, as described more fully in

[783] While the statute refers to Hospital Compare, the name has been changed to Care Compare. Now called Care Compare, the website continues to serve the purpose of displaying quality data submitted for the Hospital Readmissions Reduction Program.

section V.H.1.b. of this final rule, to suppress all of the measures in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction Domains for the FY 2022 program year because we have determined that circumstances caused by the COVID–19 PHE have affected those measures significantly, and to adopt a special scoring and payment rule for that program year. Under this special rule for FY 2022, which we would codify in our regulations at § 412.168, we would calculate measure rates for all measures, including the measures we proposed to suppress, but would only calculate achievement and improvement scores for the measures in the Clinical Outcomes Domain, which we did not propose to suppress for FY 2022. We would also calculate domain scores for the Clinical Outcomes Domain but because that domain is only weighted at 25 percent of the TPS and we would have no other domain scores, we would not calculate total performance scores (TPSs) for hospitals. Finally, we would reduce each hospital's base-operating DRG payment amount by 2 percent, as required under section 1886(o)(7)(B) of the Act, but because no hospital would receive a TPS for FY 2022, we would assign to each hospital a value-based incentive payment percentage that results in a value-based incentive payment amount that matches the 2 percent reduction to the base operating DRG payment amount. The net result of these payment adjustments would be neutral for hospitals. That is, a hospital's base operating DRG payment amount would remain unchanged for FY 2022.

We would still provide confidential feedback reports to hospitals on their FY 2022 measure rates on all measures to ensure that they are made aware of the changes in performance rates that we have observed. We would also publicly report Q3 and Q4 2020 data with appropriate caveats noting the limitations of the data due to the PHE for COVID–19. We noted that, due to operational complications associated with extended deadlines for Q3 2020 data submissions for the HCAHPS and HAI measures granted in response to the system issues as well as the proposed changes in the FY 2022 scoring methodology,[784] and in order to allow enough time for the appropriate notice and comment period process, we may not be able to provide hospitals with the feedback reports for FY 2022 until after August 1, 2021. We intend to provide hospitals with these feedback reports for FY 2022 as soon as possible and estimate that we will be able to provide reports before the end of 2021.

For the FY 2023 program year, we proposed to suppress only one measure, MORT–30–PN because we have determined that circumstances caused by the COVID–19 PHE have affected this measure significantly, but we did not propose to adopt a special scoring and payment rule for that program year (86 FR 25470). Instead, the scoring and payment rules we previously adopted at § 412.160 through 412.165 would apply. The FY 2024 and FY 2025 program years also use CY 2020 data, but we did not propose to suppress the MORT–30–PN measure in the FY 2024 and FY 2025 program years at this time. We will continue to analyze this data and will address suppression of MORT–30–PN for additional program years in future rulemaking.

In developing the measure suppression provision, we considered what circumstances caused by the PHE for COVID–19 would affect a quality measure significantly enough to warrant its suppression in the Hospital VBP Program (86 FR 25471). We stated our belief that significant deviation in measured performance that can be reasonably attributed to the PHE is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we stated our belief that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 pandemic, we stated our belief that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols, may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also noted that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new disease or conditions. Finally, we stated our belief that, as evidenced during the COVID–19 pandemic, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or facility-level case mix may result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress a Hospital VBP Program measure for one or more program years where the baseline or performance period of the measure overlaps with the PHE for COVID–19. We proposed to adopt these Measure Suppression Factors for use in the Hospital VBP Program and, for consistency, the following other value-based purchasing programs: Hospital Readmissions Reduction Program, HAC Reduction Program, and Skilled Nursing Facility Value-Based Purchasing Program. We stated our belief that these Measure Suppression Factors will help us evaluate the Hospital VBP Program's measures and that their adoption in the other value-based purchasing programs, as previously noted, will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are as follows:

- Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.
- Rapid or unprecedented changes in—
  - ++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
  - ++ The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.
- Significant national shortages or rapid or unprecedented changes in—
  - ++ Healthcare personnel;
  - ++ Medical supplies, equipment, or diagnostic tools or materials; or
  - ++ Patient case volumes or facility-level case mix.

We also considered alternatives to this proposed policy that could fulfill our objective to not penalize hospitals for measure results that are distorted due to the PHE for COVID–19. As previously noted, the country continues to grapple with the effects of the COVID–19 PHE, and in March 2020, CMS issued a nationwide, blanket Extraordinary Circumstances Exception (ECE) for all hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the COVID–19 PHE. This blanket ECE excepted data reporting requirements for Q1 and Q2

[784] All Programs (IQR, OQR, PCH, Validation, VBP, eCQM, HACRP, ESRD QIP) Subject: Q3 2020 Data Submission Deadline Extension for Certain Medicare Quality Reporting and Value-Based Purchasing Programs, available at: *https://www.cms.gov/files/document/2020-12-inpatient-quarter-3-2020-extension-listserve-final.pdf.*

2020 data, including excepting the use of claims data, HCAHPS survey data, and data collected through the CDC's web-based surveillance system for this data period. Quality data collection resumed on July 1, 2020. We considered extending this blanket ECE for Q3 and Q4 2020. This alternative would have protected hospitals from having their quality data used for quality scoring purposes if those data were affected significantly by the COVID–19 PHE. However, this option would have made hospital quality data collection and reporting to CMS no longer mandatory and would have left us with no comprehensive data available for use in providing confidential performance feedback to hospitals or monitoring for purposes of deciding whether programmatic changes are necessary to adequately respond to the PHE.

As an alternative to the proposed quality measure suppression policy, we also considered not suppressing any measures under the Hospital VBP Program. However, this alternative would mean assessing hospitals using quality measure data that has been significantly affected by the COVID–19 PHE. Additionally, given the geographic disparities in the COVID–19 PHE's effects, we stated in the proposed rule that we believe that if we do not adopt a policy to suppress measures that have been significantly affected by the PHE for COVID–19, hospitals in regions that are more heavily impacted by the COVID–19 PHE will be at a disadvantage when compared to hospitals in regions that are either not as heavily impacted, or are heavily impacted at a different point in the pandemic.

We viewed the measure suppression proposal as a necessity to ensure that the Hospital VBP Program does not reward or penalize hospitals based on circumstances caused by the PHE for COVID–19 that the Program's measures were not designed to accommodate. We intended for policy to provide short-term relief to hospitals when we have determined that one or more of the Measure Suppression Factors warrants the suppression of one or more of the Program's measures.

We invited public comment on this provision for the adoption of a measure suppression policy for the Hospital VBP Program for the duration of the PHE for COVID–19, and also on the proposed Measure Suppression Factors that we developed for purposes of the proposed policy.

We also invited comment on whether we should consider adopting a measure suppression policy in the situation of a future national PHE, and if so, whether under such a policy, we should have the flexibility to suppress certain measures without specifically proposing to do so in rulemaking. We also requested comment on whether we should in future years consider adopting any form of regional adjustment for the proposed measure suppression policy that could take into account any disparate effects of circumstances affecting hospitals around the country that would prompt us to suppress a measure. For example, COVID–19 affected different regions of the country at different rates depending on factors like time of year, geographic density, State and local policies, and health care system capacity. In future years and for future PHEs, should they arise, we also requested commenters' feedback on whether we should, rather than suppress a measure completely for scoring and payment purposes, consider a suppression policy with more granular effects based on our assessment of the geographic effects of the circumstances, and if so, how region-based measure suppression could be accounted for within the program's scoring methodology.

The comments we received on our proposals and other requests for comments, as well as our responses, are set forth below.

Comment: Many commenters expressed support for our proposed measure suppression policy, agreeing with our stated goal of ensuring that hospitals are not rewarded or penalized for their quality performance based on non-representative data. Commenters encouraged us to consult with stakeholders on any subregulatory policy changes on this topic in the future, including any potential changes to the Measure Suppression Factors, and requested that we explain the effects of any changes to the Measure Suppression Factors in detail. Some commenters recommended that we ensure that the suppression policy does not unintentionally penalize hospitals.

Response: We thank the commenters for their support. We acknowledge commenters' concern that the suppression policy should not unintentionally penalize hospitals. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule and section V.H.1.b of this final rule, we proposed to suppress measures for purposes of scoring and payment adjustments because of our concern that we could be unable to make fair, national comparisons of hospitals across the country.

Comment: Some commenters expressed concerns about our proposed suppression policy. Several commenters argued that we should not publicly report suppressed data, suggesting that data unfit to determine payments should not be publicly reported, while others suggested that we should note clearly that any publicly reported data has been affected by the COVID–19 PHE.

Response: We believe it is important to balance fairness in value-based payments with the public's need for transparency. Therefore, we intend to make the data publicly available. We understand the commenters' concern about publicly reporting data that was gathered by hospitals during the COVID–19 PHE; however, we will make clear in the public presentation of any data on a suppressed measure that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the COVID–19 PHE. We will appropriately caveat the data in order to mitigate public confusion and avoid misrepresenting quality of care.

Comment: Some commenters suggested that we should limit this policy to the current PHE given the unique circumstances involved in the COVID–19 pandemic. A few commenters expressed concerns about CMS being empowered to implement scoring adjustments and payment changes outside of rulemaking, and worried that comparisons between suppressed and unsuppressed scores would be unfair.

Response: We did not propose to apply this policy beyond the COVID–19 PHE. Any scoring adjustments or payment changes that might address a different, future fiscal year of the program due to the COVID–PHE or another type of emergency would be proposed through rulemaking. We acknowledge the commenters' concerns about potentially unfair comparisons and will consider for future rulemaking any such issues we identify.

Comment: A few commenters requested additional information regarding how CMS plans to refresh the Overall Hospital Quality Star Ratings and HCAHPS Star Ratings when only Q3 and Q4 of CY 2020 data are scheduled to be publicly reported.

Response: We are continuing to evaluate the data impacts and will provide information on future refreshes to the Overall Hospital Star Ratings and HCAHPS Star Ratings when available. Information will be provided through the Overall Hospital Star Ratings' and HCAHPS Star Ratings' previously established communication channels.

Comment: Several commenters recommended that we study the effects of the measure suppression policy and the Measure Suppression Factors to

inform any suppression policies for future PHEs and that we work with stakeholders before adopting additional measure suppression policies. A commenter recommended that we include more flexible language in our suppression factors to account for our evolving understanding of COVID–19, while another commenter suggested that we continue monitoring the effects of COVID–19 on 2021 quality performance and consider updating measure specifications to exclude COVID–19 patients or change our risk adjustment models. Other commenters suggested that we monitor the shorter performance periods carefully, as well as the effects of the policy on future benchmarking, and that we assess the indirect effects that the COVID–19 PHE has had on all aspects of medical care delivery.

Response: We share commenters' concerns about the potential long-term effects of the measure suppression policy, including the Measure Suppression Factors. While we appreciate the commenter's suggestion that we incorporate more flexibility into the Measure Suppression Factors, we believe the specificity with which we proposed them was necessary to provide hospitals and other members of the stakeholder community with clear insight into the decision-making process that we employed in response to the COVID–19 PHE. We agree with commenters that we should monitor the PHE's ongoing effects carefully and we will work with measure developers to refine measure specifications as circumstances warrant. We will also assess performance periods, benchmarks, and other effects of the COVID–19 PHE carefully and welcome stakeholders' continuing feedback as we continue responding to the PHE.

Comment: Some commenters recommended that we refine our proposed Measure Suppression Factors. Some commenters suggested that we define them more precisely to be fully transparent with the factors' terms and effects, arguing that we have not defined what we consider to be ''significant'' deviation in national performance on a measure during a PHE. A commenter also argued that the Measure Suppression Factors should be focused on effects on Medicare beneficiaries, not on providers or circumstances within the control of providers. A commenter suggested that we consider suppressing measures for individual hospitals where performance may have deviated significantly from past performance, while another commenter recommended that we ensure that the Measure Suppression Factors do not assess provider organizations' quality per se, but rather, the PHE at issue.

Response: We thank the commenters for this feedback. We believe that some level of discretion is necessary in the face of evolving circumstances like those that have confronted us in the COVID–19 PHE. In deciding which measures to suppress, and as discussed further in section VI.H.1.b. of this final rule, we examined each measure and determined that the evidence showed significant deviation in the individual measure performance data associated with the COVID–19 PHE. We believe providing the evidence for the measure suppressions is transparent and provides sufficient explanation for our rationales. We note further that we designed several of the Measure Suppression Factors to account for circumstances that could affect the health and safety of patients and healthcare personnel, and we believe that situations like personal protective equipment (PPE) shortages do affect the care provided to Medicare beneficiaries. We recommend that any individual hospitals believing that they have faced extraordinary circumstances that affect their quality performance, but that have not been addressed by the suppression policy, consider seeking an Extraordinary Circumstances Exception.[785]

Comment: Some commenters supported regional adjustments to the measure suppression policy, suggesting that we should account for disparate effects of circumstances like the COVID–19 pandemic around the country. Commenters requested that we seek stakeholders' feedback before adopting more granular suppression policies in the future. A commenter cautioned against regional adjustments, suggesting that such adjustments would not account for differences in PHE prevalence at safety-net hospitals that take on leading roles during PHEs.

Response: We thank the commenters for their feedback and will consider it for future rulemaking. We share the commenter's concern that adjustments to account for regional differences in a PHE's effects may not fully capture those differences.

Comment: Several commenters expressed support for our proposal to provide confidential performance feedback to hospitals on suppressed measures.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to adopt a measure suppression policy and the measure suppression factors described above for the duration of the COVID–19 PHE.

b. Suppression of Specific Measures for the FY 2022 or FY 2023 Program Year

(1) Background

We have conducted analyses on all Hospital VBP Program measures with the exception of the CMS PSI 90 measure to determine whether and how COVID–19 has impacted the validity of these measures. Our findings from these analyses are discussed below in the following sections. We did not conduct an analysis to determine the impact of COVID–19 on the CMS PSI 90 measure performance because the CMS PSI 90 measure would not be included in TPS calculations until FY 2023, and we proposed to remove this measure from the Hospital VBP Program beginning with FY 2023. Based on those analyses, we proposed to suppress the following measures for the FY 2022 program year:

- Hospital Consumer Assessment of Healthcare Provides and Systems (HCAHPS) (NQF #0166)
- Medicare Spending Per Beneficiary—Hospital (NQF #2158)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcomes Measure (NQF #1716)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

We additionally proposed to suppress the Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization measure (NQF #0468) (MORT–30–PN) for the FY 2023 program year. Our proposals are described in more detail in this final rule. (2) Suppression of the Hospital Consumer Assessment of Healthcare Providers and Systems

[785] For more information regarding Extraordinary Circumstances Exceptions requests under the Hospital VBP Program, please see: *https://qualitynet.cms.gov/inpatient/hvbp/participation.*

(HCAHPS) Survey Measure (NQF #0166) for the FY 2022 Hospital VBP Program Year.

We proposed to suppress the HCAHPS measure for the FY 2022 program year under proposed Measure Suppression Factor 1, significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years (86 FR 25472 through 25473). We would calculate hospitals' HCAHPS measure rates, but we would not use these measure rates to generate achievement or improvement points for this measure. Additionally, because the HCAHPS measure is the only measure included in the Person and Family Engagement domain, we would not calculate hospitals' FY 2022 domain scores for the Person and Family Engagement domain. Participating hospitals would continue to report the measure's data to CMS so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to hospitals as part of program activities to allow hospitals to track the changes in performance rates that we observe. We also intend to publicly report 2020 Q3 and Q4 2020 measure rate data where feasible and appropriately caveated.

Based on our analysis of HCAHPS data from Q1 2018 to Q3 2020, we have observed a notable decline in hospital-level HCAHPS scores. This decline is associated with the COVID–19 PHE in 2020. HCAHPS measure results are publicly reported as ''top-box,'' ''bottom-box,'' and ''middle-box'' scores, with ''top-box'' being the most positive response to HCAHPS Survey items.[786]

In order to detect the possible impact of the COVID–19 PHE on patients' experience of hospital care, we conducted an ''apples-to-apples'' analysis in which we compared hospitals' HCAHPS measure top-box scores for each quarter between Q1 2019 and Q3 2020 to their top-box scores for each of the same quarters one year earlier. For example, scores from Q1 2019 were compared to scores from Q1 2018, and scores from Q3 2020 (the most recent data available) were compared to scores from Q3 2019. The pre-COVID–19 quarters reveal the trend in HCAHPS scores prior to the onset of the pandemic. Each of these comparisons shown in Table V.H–1 includes the following:

- Official HCAHPS top-box scoring that adjusts for survey mode and patient mix.
- Restriction to hospitals with at least 25 completed surveys in each of the two matched quarters, so that the same types of hospitals that achieve 100 completes over four quarters for the Hospital VBP Program were used.
- Comparison was restricted to the same hospitals one year earlier, so that differential participation of hospitals during the excepted reporting period (Q1 and Q2 2020) did not distort results.
- Comparisons of parallel quarters were used, for example Q1 to Q1, to neutralize any seasonal effects.

TABLE V.H-1: CHANGE IN HCAHPS TOP-BOX SCORES IN MATCHED QUARTERS, FROM Q1 2019 VS. Q1 2018, TO Q3 2020 VS. Q3 2019

					COVID-19 QUARTERS		
	Change in HCAHPS Top-Box Points						
HCAHPS Measure used in Hospital VBP	Q1 2019 vs. Q1 2018	Q2 2019 vs. Q2 2018	Q3 2019 vs. Q3 2018	Q4 2019 vs. Q4 2018	Q1 2020 vs. Q1 2019	Q2 2020 vs. Q2 2019	Q3 2020 vs. Q3 2019
Communication with Nurses	**0.55*** **	**0.13***	**0.17****	-0.01	-0.04	**-1.15*** **	**-1.40*** **
Communication with Doctors	**0.32*** **	**0.13***	**0.16****	0.07	0.00	**-0.91*** **	**-1.06*** **
Staff Responsiveness	**0.71*** **	0.05	0.11	**-0.18***	**-0.82***	**-2.06*** **	**-2.54*** **
Communication About Medicine	**0.50*** **	0.01	0.08	**-0.77*** **	**-1.23*** **	**-3.27*** **	**-3.05*** **
Cleanliness	**0.59*** **	0.10	**0.23****	0.12	**-0.63*** **	**-0.92*** **	**-2.44*** **
Quietness	0.05	**-0.36*** **	**0.26****	-0.16	**0.41****	**0.54*** **	**-0.20***
Discharge Information	0.02	**-0.15****	**0.12****	**0.17****	**0.20****	**-0.79*** **	**-0.69*** **
Care Transition	**0.78*** **	**0.53*** **	**0.54*** **	**0.34*** **	**0.25****	**-2.00*** **	**-1.96*** **
Overall Rating	**0.39*** **	-0.02	0.13	0.08	**0.77*** **	-0.19	**-1.41*** **
Number of hospitals in each pair of matched quarters	3326	3250	3198	3162	1606	1701	3074

*Significant at p<0.05; **Significant p<0.005; ***Significant at p<0.0001. All bolded values are statistically significant

Notes: The Q3 2020 vs. Q3 2019 comparison is based upon ~98% of Q3 2020 hospitals that are expected to submit HCAHPS data.

Approximately 88% of hospitals in each pair of matched quarters are IPPS; approximately 12% are Critical Access Hospitals.

Standard HCAHPS scoring, including survey mode and patient-mix adjustment, has been applied.

Each column compares data from the named quarter to data from the same hospitals 1year earlier, thus accounting for seasonal effects and patient-mix adjustment.

Results show that for Q1 2019 to Q4 2019, scores generally increased compared to the same quarter one year earlier, with changes of <1 top-box point. During the first COVID–19 impacted quarter, Q1 2020, score differences were mixed, with top-box scores sometimes >1 top-box point compared to a year earlier. That is, changes between Q1 2019 and Q1 2020 were both positive and negative, with some changes exceeding 1 top-box point.

During the COVID–19 impacted quarters of Q2 2020 and Q3 2020, scores were almost always lower than a year earlier, generally by 1–3 top-box points except in the Q2 2020 vs. Q2 2019 comparison where scores increased to 0.54. These changes are statistically significant in all but one instance, often with p<0.0001, meaning that changes were too large to occur by chance more than one time in 10,000. These changes stand in sharp contrast to the patterns of small improvement prior to Q2 2020 discharges.

We note that, in accordance with the ECE granted in response to the COVID–19 PHE discussed more fully in section V.H.7 of this final rule, submission of Q1 and Q2 CY 2020 HCAHPS data was optional. However, as previously mentioned, comparisons are based on hospitals with at least 25 completed surveys in each of the two matched quarters. We do not believe that such a significant change in hospital

[786] *https://www.hcahpsonline.org/en/summary-analyses/.*

performance from the immediately preceding years for this measure would exist in the absence of the PHE for COVID–19.

Additionally, in the September 2020 IFC, we noted that we would not use any Q1 or Q2 CY 2020 data to calculate a participating hospital's TPS for the applicable fiscal years (85 FR 54835). Because the FY 2022 performance period for the HCAHPS measure is January 1, 2020 through December 31, 2020, we would only have 6 months of data (July 1, 2020 through December 31, 2020) to calculate hospital performance on this measure. We believe that the third and fourth CY 2020 data would continue to demonstrate a deviation in national performance such that scoring this measure would not be representative of national or individual hospital quality of care.

We also believe that suppressing this measure for the FY 2022 program year will address concerns about the potential unintended consequences of penalizing hospitals that treated COVID–19 diagnosed patients. Therefore, we believe it is appropriate to suppress the HCAHPS measure for the FY 2022 Hospital VBP program year.

We welcomed public comment on our proposal to suppress the HCAHPS measure for the FY 2022 program year.

Comment: Many commenters expressed support for the proposal to suppress the HCAHPS measure for the FY 2022 program year due to the impacts of the COVID–19 PHE. The commenters agreed that hospital performance would likely be non-representative of individual hospital quality and they appreciate the stability that this suppression policy provides. Additionally, the commenters supported CMS' decision to not generate improvement or performance points for this measure.

Response: We thank commenters for their support.

Comment: A few commenters did not support the public reporting of HCAHPS measure data because the data are significantly impacted by the COVID–19 pandemic. The commenters asserted that displaying this information is likely to cause confusion or misinterpretation of quality among consumers. A commenter suggested that CMS should provide hospitals with the option to opt-in to public reporting as part of their confidential feedback review.

Response: While we acknowledge commenters' concerns about publicly reporting data from the COVID–19 PHE, we disagree with the comment that we should not publicly report HCAHPS measure information for FY 2022. As noted above in section V.H.1. of this final rule, we place significant value on being as transparent as possible with the performance information that we collect, and we will make clear that that performance information was affected by the COVID–19 PHE. Further, we disagree with the suggestion to allow hospitals the option to opt-in to public reporting. We believe this may cause confusion and would provide an incomplete picture of the impact of COVID–19 on performance data.

After consideration of the public comments we received, we are finalizing our proposal to suppress the HCAHPS measure for FY 2022 as proposed.

(3) Suppression of the Medicare Spending Per Beneficiary (MSPB) Measure (NQF #2158) for the FY 2022 Hospital VBP Program Year

Pursuant to the measure suppression policy discussion in section V.H.1 of this final rule, we proposed to suppress the MSPB measure for the FY 2022 program year under proposed Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in: (i) Healthcare personnel; (ii) medical supplies, equipment, or diagnostic tools or materials; or (iii) patient case volumes or facility-level case mix (86 FR 25473 through 25474. Based on our analysis, we have found that hospitalizations involving COVID–19 overall tend to have higher mortality rates, longer lengths of stay, and higher observed, payment-standardized costs than hospitalizations without COVID–19. Based on our analysis, we believe that these rapid changes in patient case mix have significantly affected the MSPB measure. Under this proposal, we would calculate hospitals' MSPB measure rates, but we would not use these measure rates to generate achievement or improvement points for this measure. Additionally, because the MSPB measure is the only measure included in the Efficiency and Cost Reduction domain, we would not calculate hospitals' FY 2022 Efficiency and Cost Reduction domain scores. Participating hospitals would continue to report the measure's data to CMS so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report Q3 and Q4 2020 data where feasible and appropriately caveated.

We note that in the September 2020 IFC, we stated that we would not use any first or second quarter CY 2020 data to calculate TPSs for the applicable fiscal years (85 FR 54835). We also note that the MSPB Hospital measure requires a 90-day lookback period to risk adjust the data appropriately. Third quarter CY 2020 data would require a lookback period of April 1, 2020 through July 1, 2020 for risk adjustments, but this period would fall within the excepted second quarter CY 2020 data. Therefore, for the FY 2022 program year, if we were to not suppress this measure, we would only be able to use hospital admissions data from Q4 of CY 2020 to calculate hospital scores for this measure.

We conducted an analysis to assess the impact of COVID–19 on hospitalizations and several specific components of the MSPB measure, including length of stay, cost of inpatient stay, and proxy MSPB hospital episode costs (all costs from 3 days prior to admission to 30 days post-discharge). This analysis used available data from January 1, 2020 through November 22, 2020. We focused on MS–DRGs as the unit of analysis and comparison to examine the impact of COVID–19 generally on hospitalizations. We applied several data processing steps to ensure data completeness: we restricted the study population to beneficiaries with continuous enrollment in Parts A and B and with Medicare as primary payer, and who had data from three days prior to the inpatient hospital admission through 30 days post-hospital discharge during the study period. The analysis also required inpatient claims with a valid discharge date and a positive standard allowed amount to ensure that only claims that were paid under Medicare Parts A and B were captured. These data processing steps ensured the appropriate beneficiary population and data validity.

During the study period, we observed significant impacts to patient case mix due to COVID–19. The majority of hospitals (67 percent) had at least one COVID–19 hospitalization, defined as the presence of a principal or secondary diagnosis for COVID–19 on the inpatient claim. There were nearly 250,000 COVID–19 hospitalizations, representing around 4 percent of all hospitalizations during the study period. As the study period ended in November 2020, our analysis does not capture increases in COVID–19 hospitalizations over the winter period. The MS–DRG with the highest share of COVID–19 hospitalizations was MS–DRG 177 for Respiratory Infections and Inflammations with Major Complication

or Comorbidity (MCC), with over 70 percent of those admissions involving COVID–19. The effect of COVID–19 was not limited to respiratory care; in fact, we observed COVID–19 diagnoses across MS–DRGs in 25 Major Diagnostic Categories (MDCs) out of a total of 26 MDCs. The only MDC without any COVID–19 hospitalizations was MDC 15 for Newborns & Other Neonates with Conditions Originating in Perinatal Period. These results indicate that there were substantial changes to the patient case mix across the full range of care provided by hospitals due to the influx of patients with COVID–19.

Beyond the prevalence of COVID–19 amongst the hospital inpatient population, we tested the extent to which hospitalizations with COVID–19 appeared different from those without COVID–19. We found that the mean and median lengths of stays where patients were diagnosed with COVID–19 were longer compared to patients not diagnosed with COVID–19 (mean of 10 days compared to 7 days, respectively and median of 7 days compared to 5 days, respectively). We also examined various cost metrics, using payment-standardized amounts which remove the effect of the increased DRG payment weighting for hospitalizations with a COVID–19 diagnosis on the inpatient claim. The mean cost of hospitalizations with a COVID–19 diagnosis on the inpatient claim was 44 percent greater than the mean cost of hospitalizations without a COVID–19 diagnosis ($21,939 compared to $15,203). Our analysis was limited to examining inpatient hospitalizations, rather than the MSPB measure, as we focused on gaining a broader understanding of the changes to healthcare due to COVID–19. However, we did conduct some analyses to understand the post-discharge period as the MSPB measure includes a 30-day post discharge period. We compared the cost of a proxy episode by looking at the costs from 3 days prior to admission, the hospitalization, and 30 days after discharge for patients with and without a COVID–19 diagnosis on the inpatient claim. The mean cost for patients diagnosed with COVID–19 was 27 percent more than a hospital episode where the patient was not diagnosed with COVID–19 ($37,217 compared to $29,309). These results indicate that the differences in the cost of hospitalizations with and without COVID–19 extend to the post-discharge period. We believe that suppressing this measure for the FY 2022 program year would mitigate concerns about the impact of the significant changes in facility-level case mix and costs due to the PHE for COVID–19 on hospital performance and national comparability for this measure. Therefore, we believe it is appropriate to suppress the MSPB measure for the FY 2022 program year.

We welcomed public comment on our proposal to suppress the MSPB measure for the FY 2022 program year.

Comment: Many commenters supported CMS' proposal to suppress the MSPB measure and to not calculate improvement and achievement scores for FY 2022 under the Hospital VBP Program. Likewise, commenters supported not calculating Efficiency and Cost Reduction domain scores for FY 2022. A few commenters expressed gratitude for the stability provided by this proposal.

Response: We thank commenters for their support.

Comment: Several commenters did not support publicly reporting the MSPB measure data for FY 2022 because the data are significantly impacted by the COVID–19 PHE. Commenters noted that displaying this information will have limited value and is likely to cause confusion or misinterpretation of quality among consumers. A commenter suggested that CMS should provide hospitals with the option to opt-in to public reporting as part of their confidential feedback review.

Response: We believe it is important to balance fairness in value-based payments with the public's need for transparency. Therefore, we intend to make the data publicly available. We understand the commenters' concern about publicly reporting data from during the COVID–19 PHE; however, we will make clear in the public presentation of the data that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the COVID–19 PHE. We will appropriately caveat the data in order to mitigate public confusion and avoid misrepresenting quality of care.

After consideration of the public comments we received, we are finalizing our proposal to suppress the MSPB measure for FY 2022 as proposed.

(4) Suppression of the Five Healthcare-Associated Infection (HAI) Safety Measures for the FY 2022 Hospital VBP Program Year

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25474 through 25475), we proposed to suppress the five HAI Safety measures (CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) for the FY 2022 program year under proposed Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We are concerned that the COVID–19 PHE affected measure performance on the current HAI measures such that we will not be able to score hospitals fairly or reliably. We would calculate hospitals' five HAI measure rates, but we would not use these measure rates to generate achievement or improvement points for these measures. Additionally, because these five measures make up the entirety of the Safety domain, we would not calculate hospitals' FY 2022 Safety domain score. Participating hospitals would continue to report the measure data to the CDC and CMS so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would continue to provide confidential feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report CY 2020 Q3 and Q4 data where feasible and appropriately caveated.

The previously established FY 2022 performance period for the HAI measures was January 1, 2020 through December 31, 2020. We note that in the September 2020 IFC, we stated that we would not use any first or second quarter CY 2020 data to calculate TPSs for the applicable fiscal years because we were concerned with the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19 (85 FR 54835). However, we continue to be concerned about measure performance and the national comparability of such performance during the third and fourth quarter of CY 2020.

The CDC conducted an analysis which found that the CLASBI, CAUTI, and MRSA measures had statistically significant measure rate increases during the third and fourth quarter of CY 2020 as compared to the third and fourth quarter of CY 2019. We believe that this distortion in measure performance may be due to circumstances unique to the effects of the pandemic such as staffing shortages and turnover, patients that are more susceptible to infections due to increased hospitalization stays, and longer indwelling catheters and central lines. In a March comparison run

between Q4 2019 and Q4 2020 data for hospitals that submitted complete data for both quarters, there was a national percent change in the standardized infection ratio (SIR), or the primary summary measure used by the NHSN to track healthcare associated infections, of 48.1 percent for CLABSI, 18.8 percent for CAUTI and 33.8 percent for MRSA. For the SSI and CDI measures, neither measure had a statistically significant increase or decrease during the third and fourth quarter of CY 2020 as compared to the third and fourth quarter of CY 2019. For the SSI measure, the low reporting volume is due to the decrease in surgeries during the pandemic, while the CDI measure has historically been declining. Though the pandemic may not have the same clinical impact on the SSI and CDI measures, we believe that due to the low reporting volume of these two measures and for maintaining consistency of the full CDC NHSN HAI measure set, all five CDC NHSN HAI measures should be suppressed instead of just 3 of them. We are also concerned that if we were to suppress three measures in the Safety domain while continuing to score hospitals on the remaining two measures in the Safety domain, the Safety domain scores may be significantly better or significantly worse than in immediately preceding years. Therefore, we believe it is appropriate to suppress all five HAI measures in the Safety domain to ensure an accurate and reliable national comparison of performance on hospital safety.

In determining how to address the impact of the COVID–19 PHE on the five HAI measures, we also considered extending the FY 2022 performance periods for the five HAI measures so that they would include 1 full year of measure data. However, because the performance period for the FY 2022 program year began on January 1, 2020, we believe that changing the performance period after January 1, 2020 would be unfair and confusing for hospitals. Using data from CY 2019 would require us to score hospitals on data on which they have already been scored in the FY 2021 program year. Additionally, using data from CY 2021 would require us to change the performance periods for all future program years in order to avoid using the same data twice. Scoring hospitals on the same data for multiple program years may cause hospitals that have improved on their performance to be penalized more than once or allow hospitals that have not improved to be rewarded on their performance more than once. Further, changing the performance periods for these measures could create administrative costs for hospitals that would be required to change their reporting systems and workflows.

We also considered making no modifications to the program and suppressing no measure data from CY 2020 for assessing FY 2022 HAI measure scores as an additional alternative to using the measure suppression policy. This alternative would be operationally easier to implement but would mean assessing participating hospitals using quality measure data that has been impacted by the COVID–19 PHE without additional adjustments to the measures. Additionally, given the geographic disparities in the COVID–19 PHE's effects, this policy could place hospitals in regions that were hit harder by the pandemic at a disadvantage. Ultimately, we believe that our proposal to suppress the HAI measure data from CY 2020 more fairly addresses the impact of the COVID–19 PHE on participating hospitals. Therefore, in order to maintain program consistency and avoid scoring hospitals on the same data for more than one program year, we proposed to suppress all five HAI measures in the Safety domain for the entire FY 2022 program year.

We welcomed public comment on our proposal to suppress the five HAI measures for the FY 2022 program year.

Comment: Many commenters expressed support for suppressing the HAI measures in the Hospital VBP Program. A commenter believed that the impact of COVID–19 on hospitals differs across the country and the measures submitted during the PHE are distorted, unreliable, and not accurate indicators of hospital quality.

Response: We thank commenters for their support.

Comment: Several commenters supported the suppression of the HAI measures, but recommended that the measure data not be publicly reported. Commenters noted that displaying this information will have limited value and is likely to cause confusion or misinterpretation of quality among consumers.

Response: We believe it is important to balance fairness in value-based payments with the public's need for transparency. Therefore, we intend to make the data publicly available. We understand the commenters concern about publicly reporting data from during the COVID–19 PHE; however, we will make clear in the public presentation of the data that the measures have been suppressed for purposes of scoring and payment adjustments because of the effects of the COVID–19 PHE. We will appropriately caveat the data in order to mitigate public confusion and avoid misrepresenting quality of care.

Comment: A commenter did not support the proposal to suppress patient safety data related to HAIs, believing that removing any financial penalty was sufficient to address any difficulties in meeting value-based performance standards and recommended continued collection of the data.

Response: We note that the measure suppression policy provides for the continued collection and use of HAI data to calculate hospitals' five HAI measure rates, because we believe patient safety and the continued monitoring and tracking of HAIs are high priorities, however, we will not use these measure rates to generate achievement or improvement points for these measures under the FY 2022 Hospital VBP Program. Participating hospitals will continue to report the measure's data to the CDC and CMS so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We will also continue to provide confidential feedback reports to hospitals through the previously established processes, including the information available to hospitals via the CDC's National Healthcare Safety Network, as part of program activities to ensure that hospitals are made aware of the changes in performance rates that we observe, and to make the information publicly available with appropriate caveats. As described more fully in section V.H.1.a. of this final rule, we have identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating hospitals' control. We do not believe that removing the financial penalty alone for the FY 2022 program year is sufficient to address the difficulties in meeting value-based performance standards due to the impact of the COVID–19 pandemic on performance measurement for FY 2022 and instead believe that the measure suppression policy and the special scoring and payment rule for FY 2022 finalized in sections V.H.1.a and V.H.6.a. of this final rule provide the flexibility to determine if a specific measure or measures have been impacted by external factors for a program year in addition to not penalizing hospitals for performance on measures that may not reflect the quality of the care provided due to the COVID–19 pandemic. Therefore, we are finalizing our proposal to adopt a measure

suppression policy that provides for the application of measure suppression factors to help us evaluate the Hospital VBP Program's measures in section V.H.1.a. of this final rule as well as finalizing our special scoring and payment rule for FY 2022 in section V.H.6.a. We also believe that the adoption of the measure suppression policy in the other value-based purchasing programs will help ensure consistency in our measure evaluations across programs. For example, we note we are finalizing suppression of the five HAI measures in the HAC Reduction Program for the same portion of the performance period applicable to these measures; however, because the HAC Reduction Program typically uses a 2-year instead of 1-year performance period, there will be sufficient data not impacted by the COVID–19 PHE to calculate HAC Reduction Program payment adjustments for FY 2022.

After consideration of these public comments, we are finalizing our proposal to suppress the five HAI measures for FY 2022 as proposed.

(5) Suppression of the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN) Measure (NQF #0468) for the FY 2023 Program Year

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25475 through 25477), we proposed to suppress the MORT–30–PN measure beginning with the FY 2023 program year under proposed Measure Suppression Factor 2, clinical proximity of the measure's focus to the relevant disease pathogen or health impacts of the national PHE. COVID–19 is caused by SARS–CoV–2, which begins when respiratory droplets containing the virus enter an individual's upper respiratory tract. Pneumonia has been identified as a typical characteristic of individuals infected with COVID–19,[787] and our analysis based on data from CY 2020 shows that a substantial portion of the MORT–30–PN measure cohort includes admissions with either a principal or a secondary diagnoses of COVID–19. In addition, almost all of the admissions with a COVID–19 diagnosis have a principal diagnosis of sepsis; observed mortality rates for these admissions are extremely high and are substantially higher than admissions without a COVID–19 diagnosis. Finally, observed mortality rates in admissions without a COVID–19 diagnosis (using data from April 2020 through June 2020) are higher than observed mortality rates from the prior year. For the currently available data for this measure, there is a high percentage of Medicare beneficiaries with a secondary diagnosis of COVID–19 in the measure cohort during CY 2020. We would calculate hospitals' MORT–30–PN measure rates, but we would not use these measure rates to generate achievement and improvement points for this measure. We will continue to monitor the claims that form the basis for this measure's calculations to evaluate the effect of the circumstances on quality measurement and to determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that we observe.

As previously discussed, the FY 2022 MORT–30–PN performance period is September 1, 2017 through June 30, 2020. However, in the September 2020 IFC, we noted that we would not use any first or second quarter CY 2020 data to calculate TPSs for the applicable fiscal years (85 FR 54835). With this exception, the FY 2022 performance period for this measure would only be affected by a shortened performance period (September 1, 2017 through December 31, 2019) that does not use data from the COVID–19 PHE. Therefore, we have decided that it is not necessary to suppress this measure for the FY 2022 program year. However, given the ongoing status of the PHE and the impact of COVID–19 on this measure data, we proposed to suppress this measure for the FY 2023 program year.

Our analysis of the MORT–30–PN measure data showed that the MORT–30–PN cohort had a higher proportion of patients with a secondary diagnosis of COVID–19 than the cohorts for the other condition-specific mortality measures used in the Hospital VBP Program, and that these patients have a higher risk of mortality than the remainder of the patients included in the pneumonia measure cohort.

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Table V.H-2: Percent of COVID-19 Diagnoses in Mortality Measure Cohorts, March – September 2020

Mortality Measure Cohort	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020
Pneumonia	6.7	20.9	15.4	8.6	13.9	13.3	9.4
COPD	0.3	0.4	0.2	0.3	0.4	0.6	0.5
AMI	0.1	0.6	0.7	0.5	0.9	1.1	0.8
HF	0.2	0.5	0.7	0.6	0.7	0.8	0.6
THA/TKA	0.0	0.4	0.2	0.1	0.1	0.2	0.1
CABG	0.0	0.3	0.2	0.2	0.3	0.3	0.3
Stroke	0.0	1.1	1.2	0.8	1.2	1.2	1.3

[787] 957 Zheng, Jun. SARS–CoV–2: An Emerging Coronavirus that Causes a Global Threat. Int J Biol Sci. 2020; 16(10): 1678–1685. Published online 2020 Mar 15. doi: 10.7150/ijbs.45053.

Table V.H-3: Observed Mortality Rate for Admissions with Secondary Diagnosis of COVID-19 POA for the MORT-30-PN Measure, April 2020 – June 2020			
	Number of Admissions	Number of Deaths	Observed 30-Day Mortality Rate
Admissions with Secondary Diagnosis of COVID-19 POA	10,285	5,059	49.2%
Admissions without a Diagnosis of COVID-19	61,418	11,845	19.3%

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Data from September 2020 also showed that although admission volumes for the MORT–30–PN cohort were substantially lower compared to admission volumes for this cohort in September 2019, the observed mortality rates for this cohort were statistically significantly higher in September 2020 when compared to the observed mortality rates for this cohort during the same period in 2019.

Our analyses also demonstrated that almost all of the COVID–19 patients captured in the MORT–30–PN measure cohort likely represent a distinct, severely ill group of patients (with a mortality rate of 49.2 percent as compared 23.8 percent for patients without a COVID–19 diagnosis) for whom it may be difficult to adequately ascertain appropriate risk adjustment. In addition, our analyses found that the odds ratio of mortality for COVID–19 as a risk factor was very high (4.67, 95 percent confidence interval: 4.45–4.90) as compared to other diagnoses such as metastatic cancers, acute leukemia, and other severe cancers (2.16, 95 percent confidence interval: 2.05–2.28), protein-calorie malnutrition (1.64, 95 percent confidence interval: 1.57–1.71), dementia or specified brain disorders (1.58, 95 percent confidence interval: 1.51–1.64), and chronic liver disease (1.50, 95 percent confidence interval: 1.37–1.64). We also calculated the Pearson correlation between the change in observed 30-day pneumonia mortality rate and Medicare COVID–19 burden (defined as COVID–19-related hospitalizations per Medicare beneficiary) for both a 3-months (March–May) and 12-months (June–May) period. That is, we calculated the change in observed 30-day pneumonia mortality rates between March–May 2019 (3-months) and March–May 2020, and also between June 2018–May 2019 and June 2019–May 2020 (12-months). We then assessed the correlation between these changes in observed pneumonia mortality rates and Medicare COVID–19 burden. Changes in observed 30-day pneumonia mortality rates were highly and statistically significantly correlated with Medicare COVID–19 burden when analyzing the 3-month and 12-month periods (Pearson correlation of 0.77 and 0.69, respectively).

We considered whether we could exclude patients with a diagnosis of COVID–19 from the MORT–30–PN cohort, but we determined suppression will provide us with additional time and additional months of data potentially impacted by COVID–19 to more thoroughly evaluate a broader range of alternatives, given the month-to-month variation in the percent of COVID–19 diagnoses as shown in Table V.H–3. We want to ensure that the measure reflects care provided by the hospital to Medicare beneficiaries admitted with pneumonia and we are concerned that excluding a significant proportion of all eligible patients may not accurately reflect the care provided, particularly given the unequal distribution of COVID–19 patients across hospitals over time. We believe that suppressing this measure beginning with the FY 2023 program year would address this concern.

As part of our analysis, we also evaluated the impact of suppressing the MORT–30–PN measure on hospital eligibility, program scoring, and payment for FY 2023. We used data from the most recently completed program year, FY 2021, to simulate removal of the MORT–30–PN measure as compared to the baseline data.[788] For purposes of this simulation, we assumed that all other measures in the Hospital VBP Program would remain in the program and that hospital performance on these measures would remain unchanged from their historical performance on these measures. Based on this simulation, we found that the suppression of the MORT–30–PN measure resulted in less than a one percent decrease in overall eligibility for the Hospital VBP Program; the average TPS for participating hospitals decreased by 0.4 points; and the number of hospitals receiving a payment increase was reduced by one percentage point. Therefore, we believe that suppressing the MORT–30–PN measure minimizes negative impacts on the eligibility, scoring and payment distributions under the Hospital VBP Program and at this time we did not propose to make any changes to the FY 2023 scoring methodology as a result.

We invited public comment on our proposal to suppress the MORT–30–PN measure for the FY 2023 program year.

Comment: Most commenters expressed support for suppressing the MORT–30–PN measure for the FY 2023 Hospital VBP program year and agreed that the clinical proximity of pneumonia to COVID–19 was significant enough to impact hospital performance.

Response: We thank the commenters for their support.

Comment: Several commenters encouraged CMS to continue to monitor claims data to evaluate the effect of the ongoing public health emergency on quality measurement and determine if there is a need for ongoing suppression of the MORT–30–PN measure in additional fiscal years.

Response: We understand the COVID–19 PHE is ongoing and the effects may continue to impact this measure into the future. Although we are finalizing that we will suppress the MORT–30–PN measure for the FY 2023 program year, we will continue to monitor claims used in the calculation of this measure to evaluate the effect on quality measurement and to consider whether there is a need to consider additional policies for this measure in future rulemaking.

Comment: Some commenters expressed concern regarding public reporting of the MORT–30–PN measure. They noted that public reporting of the measure results may adversely impact hospital rankings and may not adequately support decision making.

Response: We acknowledge the commenters' concerns about publicly reporting data from the COVID–19 PHE and agree that publicly reported measure information is important for stakeholder decision making as well as other purposes such as transparency. We will provide confidential feedback reports to hospitals for the MORT–30–PN measure as currently specified. In these confidential reports, hospitals will be able to see which of their patients died to inform hospital quality improvement initiatives. We believe it is

[788] We note that this analysis did not include the MORT–30–CABG measure because it it not included in the Hospital VBP Program unitl FY 2022 (81 FR 56996 through 56998).

important to balance fairness in value-based payments with the public's need for transparency. Therefore, we intend to make the data publicly available. We understand the commenters concern about publicly reporting data from during the COVID–19 PHE; however, we will make clear in the public presentation of the data that the MORT–30–PN measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the COVID–19 PHE. We will appropriately caveat the data in order to mitigate public confusion and avoid misrepresenting quality of care.

After consideration of the public comments we received, we are finalizing our proposal to suppress the MORT–30–PN measure for FY 2023 as proposed.

2. FY 2022 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details. We note that in section V.H.1. of this final rule, we are finalizing our proposal to suppress several measures in the Hospital VBP Program for the FY 2022 Program Year.

Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2022 program year is two percent. Using the methodology, we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2022 is approximately $1.9 billion, based on the December 2020 update of the FY 2020 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We then calculate a value-based incentive payment adjustment factor to apply to the base operating DRG payment amount for each discharge occurring in FY 2022, on a per-claim basis. In the FY 2022 IPPS/LTCH PPS proposed rule, we published the proxy value-based incentive payment adjustment factors in Table 16 associated with the proposed rule (which is available via the internet on the CMS website) (86 FR 25477 through 25478) using the previously established scoring methodology without any modifications based off our proposals. The TPSs from the FY 2021 program year are the basis for the proxy factors. These FY 2021 performance scores are the most recently available performance scores hospitals have been given the opportunity to review and correct. We note that the FY 2021 TPSs were calculated using measure data from before the COVID–19 PHE was declared. We refer readers to sections V.H.1. and V.H.6. of this final rule for additional information on the impacts of the COVID–19 PHE on the Hospital VBP Program.

In the proposed rule, we stated that if our proposals to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount are finalized, we would not update Table 16 as Table 16A in the final rule (86 FR 25478 through 25478). We also noted that if those proposed provisions are not finalized, we would update this table as Table 16A in the final rule (which will be available on the CMS website) to reflect changes based on the March 2021 update to the FY 2020 MedPAR file. We would also update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2022 would continue to be based on historic FY 2021 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2022 program year before the FY 2022 IPPS/LTCH PPS final rule is published. Because we are finalizing our proposed measure suppression and scoring and payment policies in response to PHE due to COVID–19, we will not update Table 16 as Table 16A in this final rule.

We stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25478) that if our proposed provisions to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount are finalized, we would also not post Table 16B (which we typically do to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the applicable program year, after hospitals have been given an opportunity to review and correct their actual TPSs). Because we are finalizing our proposed measure suppression and scoring and payment policies in response to the COVID–19 PHE, we will not post a Table 16B.

We received public comments on our proposed payment policy to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operation DRG payment amount for FY 2022.

Comment: Several commenters expressed support for the FY 2022 special payment policy to avoid unfairly penalizing hospitals that were impacted by the COVID–19 PHE. A commenter noted that providing bonuses or penalties based on measure data that may be skewed would be inappropriate. A commenter also expressed appreciation for the stability provided by a budget-neutral solution for hospitals. A commenter noted that applying neutral payment adjustments for FY 2022 is both appropriate and well within CMS' statutory discretion.

Response: We thank commenters for their support.

Comment: A few commenters noted that awarding all hospitals a net-neutral payment adjustment may be penalizing hospitals that have historically performed well under the Hospital VBP Program. A few commenters noted that many hospitals rely on bonuses from the Hospital VBP Program as part of their budgets.

Response: We appreciate commenters concerns, however, the proposed flexibilities are intended to best mitigate the unprecedented effects of the COVID–19 PHE on hospitals participating in the Hospital VBP Program and our concern in the ability to make fair, national comparisons of hospitals across the country. A we noted in section V.H.1. of this final rule, we remain significantly concerned that Hospital VBP Program quality measure scores that are calculated using data submitted during the PHE for COVID–19 are distorted due to the impact of the COVID–19 PHE and will result in skewed payment incentives and inequitable payments. Though we recognize that some hospitals that may have otherwise received a positive payment incentive during a regular program year without the unexpected occurrence of the COVID–19 PHE would receive a net neutral adjustment under the proposed payment policy, we do not believe it is appropriate to penalize any hospitals with negative payment adjustments based on measure scores that we believe are distorted by the COVID–19 PHE and, thus, not reflective

of the quality of care that the measures in the Hospital VBP Program were designed to assess. As discussed in section V.H.1. of this final rule, we considered alternative approaches, but determined that the proposed approach would best serve the Hospital VBP Program and its participants as a whole to provide short-term relief when we have determined that one or more of the Measure Suppression Factors warrants the suppression of the majority of the Hospital VBP Program's measures. We view the measure suppression proposal as a necessity to ensure that the Hospital VBP Program does not reward or penalize hospitals based on circumstances caused by the PHE for COVID–19 that the Program's measures were not designed to accommodate.

After consideration of the public comments we received, we are finalizing the FY 2022 special payment policy as proposed and codifying this policy at § 412.168.

3. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41441), we finalized a revision to our regulations at § 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program, the statute does not require that the measure continue to remain in the Hospital IQR Program. We did not propose any changes to these policies.

b. Measure Removal Factors for the Hospital VBP Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446), we finalized measure removal factors for the Hospital VBP Program, and we refer readers to that final rule for details. We did not propose any changes to these policies.

c. Removal of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (NQF #0531) Beginning With the FY 2023 Program Year

We proposed to remove the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure (NQF #0531) from the Hospital VBP Program under removal Factor 8—the costs associated with the measure outweigh the benefit of its use in the program (86 FR 25478 through 25479). Factor 8 is a measure removal factor finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446).

We adopted the CMS PSI 90 composite measure (NQF #0531) in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38251 through 38256) beginning with the FY 2023 program year to encourage improvement in patient safety for all hospitals, and we also adopted a performance period for that program year that runs from July 1, 2019 through June 30, 2021. We continue to consider patient safety a high priority, but because the CMS PSI 90 measure is also used in the HAC Reduction Program, we believe removing this measure from the Hospital VBP Program will reduce the provider and clinician costs associated with tracking duplicative measures across programs. We noted in prior rulemaking that we would continue to monitor the HAC Reduction Program and Hospital VBP Program and analyze the impact of our measure selection, including any unintended consequences with having a measure in more than one program, and would revise the measure set in one or both programs if needed (82 FR 38255). Since then, we have considered the impact of having the CMS PSI 90 measure in both the HAC Reduction Program and the Hospital VBP Program. We note that the modified version of the CMS PSI 90 measure was adopted for use in the FY 2018 HAC Reduction Program as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57020). While both programs will require reporting on the same measure beginning in FY 2023, we have reconsidered whether the differences in the scoring methodologies for measuring performance in these two programs presents unneeded complexity in tracking duplicative measures while accounting for differences in applicability. For example, the scoring methodology for the CMS PSI 90 measure for the Hospital VBP Program includes comparing an individual hospital's performance during the performance period to all hospitals' performance during an established baseline period and a hospital can be awarded improvement points by comparing an individual hospital's performance during the performance period to that same individual hospital's performance from the baseline period; the HAC Reduction Program assesses performance using an equally weighted average of scores across measures included in the program and does not require a baseline period for scoring purposes. Hospitals may also incur additional cost to monitor measure performance and potential payment impact in two programs, given that each program has a different scoring methodology that applies to the same measure. We also believe removing the CMS PSI 90 measure from the Hospital VBP Program is appropriately responsive to feedback from stakeholders who have noted that using the same measure in different programs creates additional administrative costs to hospitals rather than further incentivizing improved performance. We have noted in previous years that we believe costs are multifaceted and include not only the burden associated with reporting, but also the costs CMS incurs to implement and maintain the measure in the program (83 FR 41442). Maintaining this measure in both the HAC Reduction Program and the Hospital VBP Program and applying two different scoring methodologies requires CMS to expend resources for analyzing performance and developing duplicative feedback reports for its use in both programs. For example, due to the differences in scoring methodologies between the HAC Reduction Program and the Hospital VBP Program, CMS may be required to utilize and maintain multiple versions of the CMS PSI software used to calculate PSIs and the composite measure across the two programs. Further, since 2017, we have worked to reduce regulatory burden on hospitals, lower health care costs, and enhance patient care by streamlining the quality reporting and value-based purchasing programs through the Meaningful Measures Framework. We refer readers to the FY 2019 IPPS/LTCH PPS final rule for a broader discussion of the Meaningful Measures Framework (83 FR 41147). Two of the primary objectives of the Meaningful Measures Framework are to include quality measures for which there is significant opportunity for improvement and to minimize the level of burden for providers. We recognize that the Hospital VBP Program currently uses five other patient safety-focused measures (CAUTI, CLABSI, CDI, MRSA, and SSI) that are also used under the HAC Reduction Program. As noted in prior rulemaking, we continue to monitor and analyze measures that are in both the HAC Reduction Program and Hospital VBP Program to assess the impact of having a measure in more than one program and to revise the measure set in one or both programs if needed (82 FR 38255). We focused our initial analysis on the impact of the CMS PSI 90 measure in the Hospital

VBP Program rather than the other five patient safety-focused measures because we believe it would be least burdensome to remove now, before hospitals are required to begin reporting on the measure for the FY 2023 Hospital VBP program year. Furthermore, as previously noted, the Hospital VBP Program requires that the software used to calculate measure scores between the baseline and performance period must match, whereas the HAC Reduction Program does not include baseline periods and can therefore more easily implement measure scoring. At this time, we believe there is significant opportunity for the remaining five patient safety-focused measures to continue encouraging improvement in patient safety in both the Hospital VBP Program and the HAC Reduction Program and will continue to monitor and analyze the impact of these measures and assess the need for revisions in future rulemaking. We note that the Hospital VBP Program uses the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and relies on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program.

Accordingly, for the previously discussed reasons, we proposed to remove the CMS PSI 90 measure from the Hospital VBP Program beginning with the FY 2023 program year.

We welcomed public comment on this proposal to remove the CMS PSI 90 measure beginning with FY 2023.

Comment: Many commenters expressed support for the removal of the CMS PSI 90 measure. Many commenters expressed agreement with the removal of the CMS PSI 90 measure under removal Factor 8, the costs associated outweigh the benefit to the program, believing the measure's duplicative reporting increases burden and administrative costs; it does not incentivize or improve quality care; and is a composite measure that does not readily identify individual components for improvement. A commenter noted that the CMS PSI 90 measure is a flawed measure. A commenter expressed significant concerns about the measure's construction and its ability to provide actionable information to providers. A commenter expressed concerns that some components of the CMS PSI 90 measure focus on surgical care which can disadvantage hospitals with larger volumes of surgical care.

A few commenters recommended removal of the CMS PSI 90 measure from other quality programs, including the HAC Reduction Program and all other quality programs. A commenter specifically supported the measure's removal in the Hospital VBP Program and retention in the HAC Reduction Program.

Response: We thank the commenters for their support. We note that we did not propose to remove the CMS PSI 90 measure in the HAC Reduction or other quality programs in the FY 2022 IPPS/LTCH PPS proposed rule and believe that maintaining the CMS PSI 90 measure in the HAC Reduction Program is necessary to continue tracking hospital quality on important patient safety and adverse event outcomes and to maintain a strong financial incentive focused on patient safety.

Comment: Many commenters did not support the removal of the CMS PSI 90 measure. A few commenters stated that the CMS PSI 90 measure is directly tied to safety by providing a representative picture of hospital safety and driving the focus of safety, and therefore, the measure should be retained to continue prioritizing patient safety.

Response: We appreciate the commenters concerns and note that we continue to consider patient safety a high priority. We agree that the CMS PSI 90 measure is an important measure and note that it remains in use in the HAC Reduction Program where it accounts for 16 percent of the Total HAC Score as one of the six equally-weighted measures that comprise the HAC Reduction Program measure set. We note the equal weighting scoring methodology in the HAC Reduction Program allows for the CMS PSI 90 measure to have greater weight in the calculation of the Total HAC Score compared to the weight of the CMS PSI 90 measure in Hospital VBP Program. In addition, under the HAC Reduction Program, if a hospital does not have sufficient data to score one or more of the five HAI measures, the CMS PSI 90 measure could be assigned an even greater portion of the Total HAC Score. In comparison, under the Hospital VBP Program, the CMS PSI 90 measure is one of 14 measures and is included in the Safety domain, which is weighted at 25 percent of the TPS, along with five HAI measures, which results in the CMS PSI 90 measure accounting for approximately 4 percent of the TPS. This potentially allows a hospital to not perform well on the CMS PSI 90 measure and the Safety domain, and still do well in the Hospital VBP Program if they perform well relative to other hospitals on the other measures and domains in the program We believe the greater weight attributed to the CMS PSI 90 measure in the HAC Reduction Program, and the risk of a hospital ranking within the worst-performing quartile of hospitals under the HAC Reduction Program by not performing well on the CMS PSI 90 measure, will continue to promote and prioritize patient safety for hospitals. Furthermore, under the HAC Reduction Program's payment methodology, because the penalty is applied to the worst-performing quartile of hospitals after ranking them based on their respective Total HAC Scores, if a hospital which did not receive a penalty does not continue to improve their performance on the measures while other hospitals continue to make improvements, over time such a hospital will worsen in rank and be at risk for falling within the worst-performing quartile and being penalized. Additionally, with only six measures in the HAC Reduction Program, improvement on a single measure, such as the CMS PSI 90 measure, can have a greater impact on whether a hospital receives a penalty under the HAC Reduction Program. That is, a hospital that may receive a penalty under the HAC Reduction Program can improve their performance on the CMS PSI 90 measure and increase their chances of not receiving a penalty under the HAC Reduction Program more so than the impact on their TPS under the Hospital VBP Program. In addition, hospitals' performance on the CMS PSI 90 measure will continue to be publicly reported on the *Care Compare* website and be used in the Overall Hospital Star Ratings.

We also believe there is significant opportunity for the remaining five patient safety-focused measures in the Hospital VBP Program to continue encouraging improvement in patient safety in both the Hospital VBP Program and the HAC Reduction Program along with the continued use of the CMS PSI 90 measure in the HAC Reduction Program and public reporting of hospital performance information on the *Care Compare* website. In addition, as part of our commitment to patient safety, we are developing new digital quality measures that use data from hospital EHRs that would assess various aspects of patient safety in the inpatient care setting. For example, two recently developed measures, Hospital Harm-Severe Hyperglycemia eCQM (NQF #3533e) and Hospital Harm-Severe Hypoglycemia eCQM (NQF #3503e) have been proposed and are being finalized for the Hospital IQR Program, as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25076) and in

section X.C.5.d and IX.C.5.e of this final rule. In addition to finalizing the Severe Hyperglycemia and Severe Hypoglycemia patient safety measures in this rulemaking cycle, we will also consider a composite harm measure which includes several patient safety and harm measures when all other harm measures such as pressure injury, falls with injury, acute kidney injury, and medication related bleeding are fully developed.

Comment: A commenter noted there are multi-faceted benefits to retaining measures in multiple value-based purchasing programs. A commenter stated that the measure should be retained because there are important differences between the Hospital VBP Program and HAC Reduction Program.

Response: We believe removing the CMS PSI 90 measure from the Hospital VBP Program is appropriately responsive to feedback from stakeholders who have noted that using the same measure in different programs including different software versions of the measure has created additional administrative costs to hospitals rather than further incentivizing improved performance. We also note, as discussed, the difference in CMS PSI 90 measure weight in the HAC Reduction Program compared to the Hospital VBP Program, and we believe that retaining the measure in the HAC Reduction Program where the CMS PSI 90 measure is weighted at approximately 16 percent of the Total HAC Score, as well as continued public reporting of hospitals' CMS PSI 90 performance, will continue to incentivize hospitals to maintain a strong focus on patient safety even after removal of the measure from the Hospital VBP Program.

Comment: A commenter disagreed with the removal of the CMS PSI 90 measure and the rationale CMS uses under Factor 8—the costs associated outweigh the benefit to the program—to propose removal of CMS PSI 90 believing that the costs of maintaining the CMS PSI 90 measure in two programs is minimal compared to serious harms, errors, and preventable death, and considering the overall financial costs to CMS and families. A commenter recommended that CMS retain the CMS PSI 90 measure, and, alternatively, if CMS removes the CMS PSI 90 measure, then CMS should adopt the PSI–03 pressure ulcer rate measure as a stand-alone measure.

Response: We remain committed to patient safety as a high priority and believe that Factor 8 is applicable and appropriate in this situation because costs are multifaceted and include not only the burden associated with reporting, with which hospitals have expressed concerns for several years, but also the costs CMS incurs to implement and maintain the measure in the program. We have evaluated having duplicative measures in these two programs and believe removing this measure from the Hospital VBP Program will reduce the provider and clinician costs associated with tracking duplicative measures, while continued use of the measure in the HAC Reduction Program and through public reporting of hospital performance information retains the focus on patient safety. We also note that maintaining the CMS PSI 90 measure in the HAC Reduction Program aligns with our interests in promoting patient safety with the scoring methodology of the HAC Reduction Program weighting the CMS PSI 90 measure at approximately 16 percent of the total performance score and believe this will help drive hospital behavior focused on reducing complications. While we did not propose to adopt the PSI–03 pressure ulcer rate measure in the FY 2022 IPPS/LTCH PPS proposed rule, we agree that this is an important topic and are working with a measure developer to develop the Hospital Harm-Pressure Injury electronic clinical quality measure (eCQM) for potential future use. As noted, in addition to finalizing the Severe Hyperglycemia and Severe Hypoglycemia patient safety eCQMs in this final rule, we will also consider a composite measure which includes several patient safety and harm measures when all other harm measures such as pressure injury, falls with injury, acute kidney injury, and medication related bleeding are fully developed.

After consideration of the public comments we received, we are finalizing the removal of the CMS PSI 90 measure beginning with FY 2023.

d. Updates to the Specifications of Four Condition-Specific Mortality Measures and One Procedure-Specific Complication Measure Beginning With the FY 2023 Program Year To Exclude Patients Diagnosed With COVID–19

We are updating the following four condition-specific mortality measures and one procedure-specific complication measure to exclude patients with either principal or secondary diagnoses of COVID–19 from the measure denominators beginning with the FY 2023 program year.

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230)
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893)
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229)
- Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550)

We note that we do not need to update these measures for the FY 2022 program year because the only data that would have been affected by the PHE for COVID–19 is from the first and second quarters of CY 2020, which are excluded under the ECE we granted in response to the PHE for COVID–19.

The measures we have adopted for the Hospital VBP Program are not currently specified to account for how patients with a COVID–19 diagnosis might impact the quality of care assessed by those measures. To determine this impact, we analyzed the relationship between COVID–19 and the measure cohorts for each of the applicable conditions/procedures for the Hospital VBP Program measures, as previously listed (86 FR 25479 through 25480). For these measures, we calculated the Pearson correlation between changes in observed 30-day mortality rates and Medicare COVID–19 burden (defined as COVID–19-related hospitalizations per Medicare beneficiary) for both a 3-month (March–May) and 12-month (June–May) period. That is, we calculated the change in observed 30-day mortality rates between March–May 2019 (3-months) and March–May 2020, and also between June 2018–May 2019 and June 2019–May 2020 (12-months). We then assessed the correlation between these changes in observed mortality rates and Medicare COVID–19 burden. Changes in observed 30-day mortality rates showed no or modest but statistically significant correlation with Medicare COVID–19 burden when analyzing a 3-month period for the non-pneumonia measures in the Hospital VBP Program; however, there was no significant correlation for the non-pneumonia measures when analyzing the 12-month period. Because the performance periods for these measures are each three years and there is no

significant correlation between the change in mortality with Medicare COVID–19 burden over a 12-month period (using COVID-impacted data through May 2020), we believe these measure scores will be valid and equitable for use in the Hospital VBP Program.

In the FY 2015 IPPS/LTCH PPS final rule, we finalized a technical updates policy which included a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital VBP Program (79 FR 50077 through 50079). We stated that these non-substantive updates might include exclusions to a measure (citing as an example the addition of a hospice exclusion to the 30-day mortality measures) (79 FR 50078). Due to the impact of the COVID–19 PHE on the mortality and complications measures used in the Hospital VBP Program, as described previously, we are updating the MORT–30–AMI, MORT–30–CABG, MORT–30 COPD, MORT–30–HF, and COMP–HIP–KNEE measures to exclude admissions with either a principal or secondary diagnosis of COVID–19 from the measure denominators. This technical update will modify these four condition-specific mortality measures and one procedure-specific complication measure to exclude certain ICD–10 Codes that identify patients with a principal or secondary diagnosis of COVID–19 from the measure denominators but will retain the measures in the program.

We believe that excluding COVID–19 patients from the measure denominator beginning with the FY 2023 program year and subsequent years will ensure that these four condition-specific mortality measures and one procedure-specific complication measure continue to account for mortality and complication rates as intended and meet the goals of the Hospital VBP Program. Technical specifications of the Hospital VBP Program measures are provided on our website under the Measure Methodology Reports section (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*). Additional resources about the measure technical specifications and methodology for the Hospital VBP Program are on the QualityNet website (available at: *https://qualitynet.cms.gov/inpatient/hvbp*).

Comment: Most commenters expressed support for our technical measure specification updates removing patients diagnosed with COVID–19 from the denominators of the Hospital 30-Day, All-Cause, Risk-Standardized, Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization, Coronary Artery Bypass Graft (CABG) Surgery, Chronic Obstructive Pulmonary Disease (COPD) Hospitalization, Heart Failure Hospitalization, and Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) complication measures beginning with the FY 2023 program year. Exclusion of these patients from the measure denominators will ensure that patient populations in these measures remain consistent with patient populations in prior year assessments within the three-year performance period.

Response: We thank the commenters for their support of the removal of admissions with a principal or secondary diagnosis POA of COVID–19 from the denominators of these measures.

Comment: Several commenters supported excluding patients diagnosed with COVID–19 from the denominators of the four mortality measures and the complications measure, but also encouraged CMS to continue monitoring the data to assess the full impact of COVID–19 on hospital operations and quality measures and determine if future exclusions or suppressions after FY 2023 may be necessary.

Response: We understand the COVID–19 PHE is ongoing and may be impacting many aspects of the healthcare system and patient outcomes. We will continue to monitor the claims data that form the basis for these measure calculations to evaluate the effect of COVID–19 on quality measurement and to determine appropriate policies in the future.

Comment: Commenters expressed concern that removal of patients diagnosed with COVID–19 from the measure denominators may not sufficiently address the impact of COVID–19 on the health care system during the public health emergency. There are many reasons data may show a decrease in quality, including hospitals seeing a smaller and more acute population, general disruptions in care practices during the pandemic, and challenges with available resources. They encouraged CMS to consider suppression for these mortality and complication measures starting in FY 2023.

Response: Our analyses of available data to date have estimated only minimal impacts of COVID–19 on mortality and complications measure results (for measures other than pneumonia mortality) for the FY 2023 program year due to the cohort definitions. Additionally, these measures are typically three-year measures and will additionally not include six months of data (January 1, 2020 through June 30, 2020) that we excluded from measure calculations under the ECE we granted for the Hospital VBP Program in March, 2020.

Comment: Commenters noted that the mortality and complications measures could provide valuable information on the clinical effects of COVID–19 on these conditions and procedures. For this reason, they requested that CMS consider providing confidential reports that are inclusive of COVID–19 patients for learning and monitoring purposes.

Response: We agree that measure results from the complications and mortality measures provide important information for understanding the impact of COVID–19 and improving quality. We will provide hospital specific reports (HSRs) to hospitals for the five measure with the specifications modified to remove from the denominator any principal or secondary POA of COVID index admissions. In these HSRs, hospitals will be able to see which of their patients were excluded from the measures due to a qualifying COVID–19 diagnosis to inform hospital quality improvement initiatives.

Comment: Commenters expressed concern that the proposed approach of removing patients diagnosed with COVID–19 may result in the incomplete exclusion of COVID–19 patients from the measures as the approach does not account for patients whose COVID–19 infections occur after hospital discharge, but within the 30-day time window of the measures.

Response: Any publicly reported measures will exclude data from January 1, 2020 through June 30, 2020 as announced in the COVID–19 public health emergency ECE. Outside of this timeframe, we are excluding index admissions (from the denominator) that have a principal or secondary diagnosis present on admission (POA), of COVID–19 using the COVID–19 specific ICD–10 code (U07.1). To align with changes for the readmission measures in the Hospital Readmissions Reduction Program (see section V.G.6.c of this final rule), and in response to the public comments received, we will also remove numerator events for readmissions related to COVID–19 for the four medical complications that are part of the outcome inclusion criteria for the COMP–HIP–KNEE measure. The four medical complication outcomes that this applies to are: (1) Acute myocardial infarction (AMI) during a subsequent inpatient admission that occurs within seven days from the start of the index admission; (2) pneumonia or other acute

respiratory complication during a subsequent inpatient admission that occurs within seven days from the start of the index admission, (3) sepsis/septicemia/shock during a subsequent inpatient admission that occurs within seven days from the start of the index admission, and (4) pulmonary embolism during the index admission or a subsequent inpatient admission within 30 days from the start of the index admission. In these cases, readmissions with a principal or secondary diagnosis POA of COVID–19 (U07.1) will be removed from the numerator. We appreciate the commenters suggestion to remove post-discharge mortality events due to COVID–19, however, the data sources that are used to identify the outcome do not specify the cause of death.

Comment: Some commenters did not support removal of COVID–19 patients from the denominators of the mortality and complications measures unless the only cases that are excluded are those cases where the COVID–19 diagnosis was present on admission (POA). The commenters believe hospitals should be accountable for the transmission of COVID–19 and for deaths of patients who were infected while in the hospital. Although the commenters expressed recognition of the many challenges hospitals have endured, they felt hospitals' ability to prevent the spread of COVID–19 infection within their walls is of enormous importance to the public and to health care workers.

Response: We agree with the commenters and note that almost all of the admissions with a COVID–19 diagnosis within the cohorts for the mortality and complication measures in the Hospital VBP Program represent COVID–19 as a secondary diagnosis present on admission (POA). We are clarifying here that patients who contract COVID–19 in the hospital (that is, patients who do not have a COVID–19 diagnosis POA, but subsequently receive a COVID–19 diagnosis during their hospital stay) and die represent a quality signal that the hospital should have taken steps to prevent the spread of COVID–19 infection within their facility, and therefore these patients will be included in the measure. In rare cases, due to the MORT–30–CABG and COMP–HIP–KNEE procedural measures' cohort definitions based upon procedure codes, an admission with a COVID–19 principal diagnosis may theoretically be within the cohort. We are therefore clarifying that we are removing index admissions with a principal, or secondary COVID–19 diagnosis POA.

e. Summary of Previously Adopted Measures for FY 2022 Through FY 2025 Program Years

We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58849 through 58850) for summaries of previously adopted measures for the FY 2023 and FY 2024 program years, and to the tables in this section showing summaries of previously adopted measures for the FY 2023, FY 2024, and FY 2025 program years. We proposed to remove the CMS PSI 90 measure from the Hospital VBP Program beginning with the FY 2023 program year. We also proposed to suppress the HCAHPS, MSPB, and HAI measures for the FY 2022 program year, and to suppress the MORT–30–PN measure for FY 2023. We did not propose to add new measures at this time. Because these measure proposals are being finalized as proposed, the Hospital VBP Program measure set for the FY 2022, FY 2023, FY 2024 and FY 2025 program years would contain the following measures:

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Table V.H-4: Summary of Measures for the FY 2022 Program Year with Finalized Measure Proposals		
Measure Short Name	**Domain/Measure Name**	**NQF #**
Person and Community Engagement Domain		
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)
Safety Domain		
CAUTI*	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI*	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI*	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550

Table V.H-4: Summary of Measures for the FY 2022 Program Year with Finalized Measure Proposals		
Measure Short Name	**Domain/Measure Name**	**NQF #**
Efficiency and Cost Reduction Domain		
MSPB*	Medicare Spending Per Beneficiary (MSPB) – Hospital	2158

* Per section V.H.1.b. of this final rule, we are finalizing our proposal to suppress the HCAHPS, MSPB, and HAI measures for the FY 2022 program year.

Table V.H-5: Summary of Measures for the FY 2023, FY 2024, and FY 2025 Program Years with Finalized Measure Proposals		
Measure Short Name	**Domain/Measure Name**	**NQF #**
Person and Community Engagement Domain		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN* (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468

Table V.H-5: Summary of Measures for the FY 2023, FY 2024, and FY 2025 Program Years with Finalized Measure Proposals		
Measure Short Name	**Domain/Measure Name**	**NQF #**
MORT-30-COPD*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) – Hospital	2158

* Per section V.H.1.b.(5) and V.H.2.d. of this final rule, we are finalizing our proposal to suppress the MORT-30-PN measure for FY 2023 and exclude patients with a principal or secondary diagnosis POA of COVID-19 from the measure denominators in the remaining condition-specific mortality measures and the procedure-specific complication measure. We are also removing certain applicable readmissions from the outcome (numerator) of the procedure-specific complication measure.

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4. Previously Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for a previously finalized schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41466 through 41469), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42393 through 42395), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58850 through 58854) for additional previously adopted baseline and performance periods for the FY 2023 and subsequent program years. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to remove the CMS PSI 90 measure and to suppress the MORT–30–PN measure for the FY 2023 program year (86 FR 25478 through 25479; 86 FR 25475 through 25477).

b. Updated Baseline Periods for Certain Measures Due to the Extraordinary Circumstances Exception Granted in Response to the COVID–19 PHE

(1) Background

We previously finalized baseline and performance periods for the FY 2023, 2024, 2025, 2026, and 2027 program years for all the measures included in the Hospital VBP Program, and we refer the reader to Table V.H–5 for those previously adopted baseline and performance periods. However, subsequent to finalizing those baseline periods, and as described further in section V.H.7. of this final rule, we granted an ECE in response to the COVID–19 PHE and stated that we will not use any first or second quarter of CY 2020 measure data that was voluntarily submitted for scoring purposes under the Hospital VBP Program.

If we simply removed the first and second quarter of CY 2020 measure data from the previously finalized baseline periods for the FY 2024 program year the baseline period for certain measures included in the Hospital VBP Program would only be 6 months, which is too short for purposes of calculating reliable baseline period scores.

Accordingly, to ensure that we have a sufficient quantity of data for baselining purposes, we proposed and are finalizing several updates to the baseline periods in this final rule for the FY 2024 program year and we refer readers to section V.H.4.b. of this final rule for further discussion of these updates. We believe that the previously established baseline periods for FY 2022, FY 2025, and FY 2026 program years are not impacted. There are also measures whose quantity of data for baselining purposes would be impacted by the ECE for the FY 2027 program year. However, for these measures, we believe 30 and 33-month baseline periods still provide enough data to reliably calculate baseline scores.

(2) Updated FY 2024 Baseline Period for the Person and Community Engagement Domain Measure (HCAHPS Survey)

For the Person and Community Engagement Domain Measure (HCAHPS Survey), we finalized that the baseline period for the FY 2024 program year would be January 1, 2020 through December 31, 2020, but the removal of the January-June data would only leave us with 6 months of data (86 FR 25483). We believe that using at least a full year for data collection provides high levels of data accuracy and reliability for scoring hospitals on this measure (76 FR 2458). Therefore, we proposed to use a baseline period of January 1, 2019 through December 31, 2019 so that we have a full year of data (86 FR 25483). This baseline period would be paired with the previously finalized performance period of January 1, 2022 through December 31, 2022. We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2024 scoring. We selected this

revised data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal effects.

We noted that this new proposed baseline period would not include the third or fourth quarters of 2020, even though those quarters were not included in the ECE. However, our internal analyses indicated that the average number of completed surveys, and thus average reliability of the measure as a whole, is higher when based on four consecutive quarters as opposed to two quarters of HCAHPS data. In addition, because hospitals must report at least 100 completed surveys for a performance period to receive an HCAHPS measure score, reducing the baseline period from 12 to 6 months would result in fewer hospitals, especially smaller hospitals, being able to report 100 surveys for the performance period. We estimated that 11 percent of the hospitals that would be able to achieve 100 completed surveys over four quarters would be unable to do so in two quarters. As a result, we believe using four consecutive quarters of data for the baseline period will provide a higher level of data accuracy and reliability for scoring hospitals on the HCAHPS Survey.

(3) Updated FY 2024 Baseline Period for the Safety Domain Measures

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized the performance period for all measures in the Safety domain to run on the calendar year two years prior to the applicable program year and a baseline period that runs on the calendar year four years prior to the applicable program year for the FY 2019 program year and subsequent program years. For FY 2024, the baseline period for the Safety Domain Measures would be January 1, 2020 through December 31, 2020, but the removal of data impacted by the ECE from January to June of 2020 would only leave us with 6 months of data. We believe that using at least a full year for data collection provides high levels of data accuracy and reliability for scoring hospitals on measures (76 FR 2458). Therefore, we proposed to update the FY 2024 baseline period for the Safety domain measures from January 1, 2020 through December 31, 2020 to January 1, 2019 through December 31, 2019 so that we have a full year of data (86 FR 25483). We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2024 scoring. We selected this data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal effects.

(4) Updated FY 2024 Baseline Period for the Efficiency and Cost Reduction Domain Measure

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized a 12-month performance period for the MSPB measure that runs on the calendar year two years prior to the applicable program year and a 12-month baseline period that runs on the calendar year four years prior to the applicable program year for the FY 2019 program year and subsequent years. For FY 2024, the baseline period for the MSPB measure would be January 1, 2020 through December 31, 2020, but the removal of data impacted by the ECE from January to June of 2020 would only leave us with 6 months of data. We believe that using at least a full year for data collection provides high levels of data accuracy and reliability for scoring hospitals on measures (76 FR 2458). Therefore, we proposed to update the FY 2024 baseline period for the MSPB measure from January 1, 2020 through December 31, 2020 to January 1, 2019 through December 31, 2019 so that we have a full year of data (86 FR 25483 through 25484). We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2024 scoring. We selected this data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal affects.

We welcomed public comment on our proposals to update the FY 2024 baseline periods for the measures included in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction domains.

Comment: Many commenters supported CMS' proposal to change the FY 2024 baseline periods for the Person and Community Engagement, Safety, and Efficiency and Cost Reduction Domains. Commenters agreed with the approach of using a full year of 2019 data rather than 6 months of 2020 data for the purposes of data accuracy and reliability.

Response: We thank commenters for their support.

Comment: A few commenters recommended that CMS should continue to monitor CY 2021 performance to determine whether there is a fair and valid comparison to pre-pandemic baseline periods or if further policy updates are needed to better compare performance and improvement scores.

Response: We thank commenters for their recommendation and note that we plan to continue monitoring the impacts of the COVID–19 PHE on performance data to evaluate whether any additional flexibilities or updates are needed.

After consideration of the public comments we received, we are finalizing the updates to the FY 2024 baseline periods for measures included in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction domains as proposed.

c. Summary of Previously Adopted and Newly Updated Baseline and Performance Periods for the FY 2023 Through FY 2027 Program Years

The following tables summarize the previously adopted and newly updated baseline and performance periods.

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Table V.H-6: Previously Adopted Baseline and Performance Periods for the FY 2023 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2019 – December 31, 2019	● January 1, 2021 – December 31, 2021
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** ● COMP-HIP-KNEE	● July 1, 2013 – June 30, 2016 ● April 1, 2013 – March 31, 2016	● July 1, 2018 – June 30, 2021* ● April 1, 2018 – March 31, 2021*
Safety✦ ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2019 – December 31, 2019	● January 1, 2021 – December 31, 2021
Efficiency and Cost Reduction ● MSPB	● January 1, 2019 – December 31, 2019	● January 1, 2021 – December 31, 2021

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting*; *CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*), and then updated in the August 25th COVID-19 IFC (*85 FR 54820*). For more detailed information, see section V.H.7. of this final rule.

** Per section V.H.1.b.(5). of this final rule, we are finalizing our proposal to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section V.H.3.c. of this final rule, we are finalizing our proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

Table V.H-7: Previously Adopted and Newly Updated Baseline and Performance Periods for the FY 2024 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2019 – December 31, 2019*	● January 1, 2022 – December 31, 2022
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** ● COMP-HIP-KNEE	● July 1, 2014 – June 30, 2017 ● April 1, 2014 – March 31, 2017	● July 1, 2019 – June 30, 2022* ● April 1, 2019 – March 31, 2022*
Safety✦ ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2019 – December 31, 2019*	● January 1, 2022 – December 31, 2022
Efficiency and Cost Reduction ● MSPB	● January 1, 2019 – December 31, 2019*	● January 1, 2022 – December 31, 2022

*These performance and baseline periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting*; *CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*), and then updated in the August 25th COVID-19 IFC (*85 FR 54820*). For more detailed information, see the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25494 through 25495). As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25483 through 25484), we proposed to update the baseline periods for the measures included in the Person and Family Engagement, Safety, and Efficiency and Cost Reduction domains.

** Per section V.H.1.b.(5). of this final rule, we are finalizing our proposal to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section V.H.3.c. of this final rule, we are finalizing our proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

Table V.H-8: Previously Adopted Baseline and Performance Periods for the FY 2025 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** ● COMP-HIP-KNEE	● July 1, 2015 – June 30, 2018 ● April 1, 2015 – March 31, 2018	● July 1, 2020 – June 30, 2023 ● April 1, 2020 – March 31, 2023*
Safety✦ ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023
Efficiency and Cost Reduction ● MSPB	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting*; *CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*), and then amended in the August 25th COVID-19 IFC (*85 FR 54820*). For more detailed information, see the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25494 through 25495).

** Per section V.H.1.b.(5). of this final rule, we are finalizing our proposal to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section V.H.3.c. of this final rule, we are finalizing our proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

Table V.H-9: Previously Adopted Baseline and Performance Periods for the FY 2026 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)* ● COMP-HIP-KNEE	● July 1, 2016 – June 30, 2019 ● April 1, 2016 – March 31, 2019	● July 1, 2021 – June 30, 2024 ● April 1, 2021 – March 31, 2024
Safety✦ ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024
Efficiency and Cost Reduction ● MSPB	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024

** Per section V.H.1.b.(5). of this final rule, we are finalizing our proposal to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section V.H.3.c. of this final rule, we are finalizing our proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

Table V.H-10: Previously Adopted Baseline and Performance Periods for the FY 2027 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2023 – December 31, 2023	● January 1, 2025 – December 31, 2025
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** ● COMP-HIP-KNEE	● July 1, 2017 – June 30, 2020* ● April 1, 2017 – March 31, 2020*	● July 1, 2022 – June 30, 2025 ● April 1, 2022 – March 31, 2025
Safety✦ ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2023 – December 31, 2023	● January 1, 2025 – December 31, 2025
Efficiency and Cost Reduction ● MSPB	● January 1, 2023 – December 31, 2023	● January 1, 2025 – December 31, 2025

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting*; *CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*), and then amended in the August 25th COVID-19 IFC (*85 FR 54820*). For more detailed information, see the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25494 through 25495).

** Per section V.H.1.b.(5). of this final rule, we are finalizing our proposal to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section V.H.3.c. of this final rule, we are finalizing our proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

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5. Performance Standards for the Hospital VBP Program

a. Background

We refer readers to sections 1886(o)(3)(A) through 1886(o)(3)(D) of the Act for the performance standard requirements under the Hospital VBP Program. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program. We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50077 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58856 through 58857) for previously established performance standards for the FY 2023 program year. We note that the measure suppression proposals for the FY 2022 and FY 2023 program years, discussed more fully in section V.H.1. of this final rule, will not affect the performance standards for the FY 2022 or FY 2023 program year. However, as discussed in section V.H.6. of this final rule, we are finalizing our proposal to not generate achievement or improvement points for any suppressed measures for FY 2022.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for further discussion on performance standards for which the measures are calculated with lower values representing better performance (85 FR 58855).

b. Previously Established and Estimated Performance Standards for the FY 2024 Program Year

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472), we established performance standards for the FY 2023 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and for the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41471 through 41472), we established, for the FY 2023 program year, the performance standards for the Safety domain measure, CMS PSI 90. However, as discussed in section V.H.3.c. of this final rule, we are finalizing our proposal to remove the CMS PSI 90 measure from

the Hospital VBP Program beginning with the FY 2023 program year. For this reason, we did not provide the estimated performance standards for this measure in the proposed rule. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. As discussed in section V.H.4.b. of this final rule, we are finalizing our proposal to update the FY 2024 program year baseline periods for the measures included in the Safety, Person and Community Engagement, and Efficiency and Cost Reduction domains. Since this proposal is being finalized, according to our established methodology for calculating performance standards, we will use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2024 program year for these measures.

In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) and codified at 42 CFR 412.160, we are estimating additional performance standards for the FY 2024 program year. We noted in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25489) that the numerical values for the performance standards for the Safety and Person and Community Engagement domains for the FY 2024 program year in the following tables are estimates based on the most recently available data, and that we intended to update the numerical values in the FY 2022 IPPS/LTCH PPS final rule. The updated numerical values are in Table V.H–11.

The previously established and newly updated performance standards for the measures in the FY 2024 program year are set out in the following tables.

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Table V.H-11: Previously Established and Newly Updated Performance Standards for the FY 2024 Program Year

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain♦		
CAUTI*	0.650	0
CLABSI*	0.589	0
CDI*	0.520	0.01
MRSA Bacteremia*	0.726	0
Colon and Abdominal Hysterectomy SSI*	0.717 0.738	0 0
Clinical Outcomes Domain		
MORT-30-AMI#	0.866548	0.885499
MORT-30-HF#	0.881939	0.906798
MORT-30-PN (updated cohort)#	0.840138	0.871741
MORT-30-COPD#	0.919769	0.936349
MORT-30-CABG#	0.968747	0.979620
COMP-HIP-KNEE*#	0.027428	0.019779
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

♦ As discussed in section V.H.4.b. of this final rule, we are finalizing the updates to the FY 2024 baseline periods for measures included in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction domains to use CY 2019. Therefore, the performance standards displayed in this table for the Safety domain measures were calculated using CY 2019 data.

* Lower values represent better performance.

Previously established performance standards.

The HCAHPS Base Score is calculated using the eight dimensions of the HCAHPS measure. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (0–80 points). Each of the eight dimensions is of equal weight; therefore, the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores

of all eight Person and Community Engagement dimensions. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement Domain score that ranges from 0 to 100 points. As discussed in section V.H.4.b. of this final rule, we are finalizing our proposal to update the FY 2024 program year baseline period for the measure included in the Person and Community Engagement domain. Since this proposal is finalized, according to our established methodology for calculating performance standards, we will use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2024 program year for this measure.

Table V.H-12: Newly Updated Performance Standards for the FY 2024 Program Year: Person and Community Engagement Domain[±]

HCAHPS Survey Dimension	Floor (minimum)	Achievement Threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	53.50	79.42	87.71
Communication with Doctors	62.41	79.83	87.97
Responsiveness of Hospital Staff	40.40	65.52	81.22
Communication about Medicines	39.82	63.11	74.05
Hospital Cleanliness & Quietness	45.94	65.63	79.64
Discharge Information	66.92	87.23	92.21
Care Transition	25.64	51.84	63.57
Overall Rating of Hospital	36.31	71.66	85.39

[±] As discussed in section V.H.4.b. of this final rule, we are finalizing the updates to the FY 2024 baseline periods for measures included in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction domains to use CY 2019. Therefore, the performance standards displayed in this table for the Person and Community Engagement domain measures were calculated using CY 2019 data.

c. Previously Established Performance Standards for Certain Measures for the FY 2025 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42398 through 42399), we established performance standards for the FY 2025 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58858), we established, for the FY 2025 program year, the performance standards for the Safety domain measure, CMS PSI 90. However, as discussed in section V.H.3.c. of this final rule, we are finalizing our proposal to remove the CMS PSI 90 measure from the Hospital VBP Program starting with the FY 2023 program year. For this reason, we are not including performance standards for this measure in this final rule. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established and newly established performance standards for these measures are set out in the following table.

Table V.H-13: Previously Established Performance Standards for the FY 2025 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Safety Domain		
Clinical Outcomes Domain		
MORT-30-AMI	0.869247	0.887868
MORT-30-HF	0.882308	0.907733
MORT-30-PN (updated cohort)	0.840281	0.872976
MORT-30-COPD	0.916491	0.934002
MORT-30-CABG	0.969499	0.980319
COMP-HIP-KNEE*	0.025396	0.018159
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

d. Previously Established Performance Standards for Certain Measures for the FY 2026 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58858 through 588589), we established performance standards for the FY 2026 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time.

The previously established performance standards for these measures are set out in the following table.

Table V.H-14: Previously Established Performance Standards for the FY 2026 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Safety Domain		
Clinical Outcomes Domain		
MORT-30-AMI	0.872624	0.889994
MORT-30-HF	0.883990	0.910344
MORT-30-PN (updated cohort)	0.841475	0.874425
MORT-30-COPD	0.915127	0.932236
MORT-30-CABG	0.970100	0.979775
COMP-HIP-KNEE*	0.025332	0.017946
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

e. Newly Established Performance Standards for Certain Measures for the FY 2027 Program Year

As discussed previously, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB) for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), which is codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2027 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in the following table.

Table V.H-15: Newly Established Performance Standards for the FY 2027 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Clinical Outcomes Domain**		
MORT-30-AMI	0.877824	0.893133
MORT-30-HF	0.887571	0.913388
MORT-30-PN (updated cohort)	0.844826	0.877204
MORT-30-COPD	0.917395	0.932640
MORT-30-CABG	0.971149	0.980752
COMP-HIP-KNEE*	0.023322	0.017018
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** As discussed further in section V.H.7. of this final rule, we did not include data from Q1 and Q2 of CY 2020 in the calculation of these performance standards.

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6. Scoring Methodology and Data Requirements

a. Scoring Methodology for the FY 2022 Program Year Due to the PHE for COVID–19

As described in section V.H.1. of this final rule, we are finalizing our proposal to suppress seven measures in the Hospital VBP Program for FY 2022 and to use a special rule for FY 2022 scoring. As previously discussed, we are finalizing that we would calculate measure rates for all measures in the FY 2022 program year. For measures that we proposed to suppress, we would not use the measure rates to generate achievement and improvement points within the Hospital VBP Programs current scoring methodology. We further proposed under this special rule that we would only calculate achievement and improvement points, as well as a domain score, for the Clinical Outcomes Domain and that, because no other domains receive scores for the FY 2022 Program year, we would not award TPSs to any hospital for FY 2022.

Because no hospital would receive a TPS for FY 2022, we further proposed that we would reduce each hospital's base-operating DRG payment amount by 2 percent, as required under section 1886(o)(7)(B) of the Act, and then assign to each hospital a value-based incentive payment amount that matches the 2 percent reduction to the base operating DRG payment amount. The net result of these payment adjustments would be neutral for hospitals. We have stated that value-based payment systems should rely on a mix of standards, processes, outcomes, and patient experience measures (76 FR 26491). As such, the Hospital VBP Program scoring methodology was developed to be used with several measures across multiple domains and aims to score hospitals on their overall achievement relative to national benchmarks. However, as discussed in the measure suppression proposals in section V.H.1. of this final rule, the data from several measures is significantly impacted by the COVID–19 PHE. Awarding negative or positive incentive payment adjustment percentages using TPSs calculated using the current scoring methodology would not provide a representative score of a hospital's overall performance in providing quality of care during a pandemic.

In order to ensure that hospitals are aware of changes in their performance rates that we have observed, we proposed to provide FY 2022 confidential feedback reports that contain the measure rates we have calculated for the FY 2022 program year, along with achievement and improvement scores for the measures in the Clinical Outcomes Domain and a Clinical Outcomes Domain score. However, as previously discussed, we proposed that the measure rates and Clinical Outcome Domain performance scores would not be used to calculate TPSs for the purpose of adjusting hospital payments under the FY 2022 Hospital VBP Program.

We invited public comment on these scoring proposals for FY 2022.

Comment: Several commenters supported CMS' proposal to not calculate a total performance score to avoid unfairly penalizing hospitals that have been impacted by the COVID–19 PHE. A few commenters urged CMS to finalize the FY 2022 special scoring policy to account for the significant impact COVID–19 had on hospitals. A commenter noted that CMS is best situated to understand the effect of COVID–19 on program outcomes. A commenter noted appreciation that CMS will calculate and report measure scores where feasible and appropriate given the value of these data to hospitals for performance improvement initiatives now and for future PHEs.

Response: We thank commenters for their support and agree that the FY 2022 special scoring policy is an appropriate approach to unfairly penalizing hospitals and account for the impact of the COVID–19 PHE on hospitals.

Comment: A few commenters sought clarification on how the FY 2022 special scoring policy would affect other programs such as the Merit-based

Incentive Payment System (MIPS) that use Hospital VBP Program measures. Commenters expressed concern that the FY 2022 special scoring policy would negatively impact facility-based clinicians participating in the MIPS.

Response: We understand that the FY 2022 special scoring policy has implications for the MIPS program. Under the facility-based measurement option within MIPS, clinicians eligible for facility-based measurement, as described § 414.1380(e)(2), may have their MIPS quality and cost performance category scores based on the Total Performance Score of their affiliated hospital from the Hospital VBP Program as determined by the requirements at § 414.1380(e)(5). As described at § 414.1380(e)(1)(ii) and in the CY 2019 PFS final rule, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period. Thus, for the CY 2021 MIPS performance period/CY 2023 MIPS payment year, the Total Performance Score for FY 2022 would be applied. If a hospital does not have a Total Performance Score, facility-based measurement is not available for the MIPS eligible clinicians affiliated with that hospital. Since no hospitals will have a FY 2022 Total Performance Score, the clinicians who are normally assessed through facility-based measurement will need to identify another method of participating in MIPS for the CY 2021 MIPS performance period/CY 2023 MIPS payment year or submit an application for reweighting a performance category or categories, if applicable.

Comment: A commenter suggested that CMS establish alternative performance periods for the FY 2022 program year, noting this approach would recognize investments in and on-going costs of quality infrastructure made by hospitals that maintained strong performance on measures prior to the pandemic. A commenter suggested a more equitable way to administer the program would be to average hospitals' scores over the last two years to determine TPSs and payment incentive multipliers for FY 2022.

Response: We encourage hospitals to continue investing in and developing quality infrastructure to provide beneficiaries with high quality care, whether or not they are receiving a positive payment adjustment for a given fiscal year. In assessing approaches for mitigating the impact of the COVID–19 PHE on our quality payment programs, we considered establishing alternative performance periods. However, if we were to establish alternative performance periods for the Hospital VBP Program measures, we would be limited to data that has already been used to determine incentive payments in the past. Our preference is to avoid, where feasible, using the same data as a previous performance period in multiple program years. Hospitals that maintained strong performance on measures prior to the pandemic have been recognized through positive payment incentives distributed in prior program years, and we believe our proposed approach provides relief to hospitals impacted by the COVID–19 PHE while avoiding unfairly adjusting hospital payments.

Comment: A commenter suggested CMS should score hospitals in FY 2022 and provide positive payment adjustments for hospitals that receive a TPS that exceeds 1.0 while those hospitals that score below 1.0 be held harmless.

Response: As discussed in section V.H.1., we do not believe it would be appropriate to score hospitals and distribute incentive payments based on data that have been significantly impacted by the COVID–19 PHE. We believe that the COVID–19 pandemic has impeded effective quality measurement and because COVID–19 prevalence is not consistent across the country, hospitals located in different areas have been affected differently at different times throughout the pandemic. Under those circumstances, we remain significantly concerned that Hospital VBP Program quality measure scores that are calculated using data submitted during the PHE for COVID–19 are distorted. Therefore, we believe that scoring hospitals and providing a positive payment adjustment to any hospital would require us to provide positive payment incentives based on unreliable or potentially inaccurate TPSs, which could still penalize hospitals that were affected by holding them harmless when they might otherwise receive a positive payment adjustment in the absence of the PHE due to COVID–19. Additionally, implementing the suggested approach would be logistically infeasible to implement as the funds to pay for positive payment adjustments would need to come from the reduction of payments to other participating hospitals. Otherwise, the positive payment adjustments would be deducted from the Medicare trust fund, which could threaten the stability and sustainability of the Hospital VBP Program as well as other programs funded by the Medicare trust fund.

Comment: A commenter urged CMS to use the previously established scoring methodology to score hospitals for FY 2022 because monitoring and tracking key measures using pandemic data is an important component of understanding an organization's ability to serve its patients.

Response: We agree that it is important to continue tracking key metrics during the COVID–19 PHE. As part of the measure suppression policy, we proposed that hospitals would continue to collect and submit measure data to monitor quality and so that we are able to provide hospitals with confidential feedback reports and publicly report these data with appropriate caveats. We believe we are capable of monitoring and tracking key measures through this continued data collection and calculation of measure rates. Additionally, because the data will be publicly reported, other stakeholders will also be able to monitor and track these measures.

After consideration of the public comments we received, we are finalizing the FY 2022 Hospital VBP Program scoring policies as proposed.

b. Domain Weighting for the FY 2023 Program Year and Subsequent Years for Hospitals That Receive a Score on All Domains

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the Hospital VBP Program for the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. We did not propose any changes to these policies.

c. Domain Weighting for the FY 2023 Program Year and Subsequent Years for Hospitals Receiving Scores on Fewer Than Four Domains

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085) we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, for the FY 2017 program year and subsequent years. Hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085). We did not propose any changes to these policies.

d. Minimum Numbers of Measures for Hospital VBP Program Domains

We refer readers to the 2018 IPPS/LTCH PPS final rule (82 FR 38266) for our previously finalized requirements

for the minimum numbers of measures for hospitals to receive domain scores. We did not propose any changes to these policies.

e. Minimum Numbers of Cases for Hospital VBP Program Measures

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53610); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41465 through 41466); the FY 2020 IPPS/LTCH PPS final rule (84 FR 42399 through 42400; and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58859 through 58860). We did not propose any changes to these policies.

(2) Summary of Previously Adopted Minimum Numbers of Cases

The previously adopted minimum numbers of cases for these measures are set forth in the following table.

Table V.H-16: Previously Adopted Minimum Case Number Requirements for the FY 2024 Program Year and Subsequent Years

Measure Short Name	Minimum Number of Cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain	
MORT-30-AMI	Hospitals must report a minimum number of 25 cases.
MORT-30-HF	Hospitals must report a minimum number of 25 cases.
MORT-30-PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT-30-COPD	Hospitals must report a minimum number of 25 cases.
MORT-30-CABG	Hospitals must report a minimum number of 25 cases.
COMP-HIP-KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

f. Summary of Previously Adopted Administrative Policies for NHSN Healthcare-Associated Infection (HAI) Measure Data

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42400 through 42402), we finalized our proposal to use the same data to calculate the CDC NHSN HAI measures for the Hospital VBP Program that the HAC Reduction Program uses for purposes of calculating the measures under that program, beginning on January 1, 2020 for CY 2020 data collection, which would apply to the Hospital VBP Program starting with data for the FY 2022 program year performance period. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42402), we also finalized our proposal for the Hospital VBP Program to use the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and to rely on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program. We did not propose any changes to these policies.

7. Extraordinary Circumstance Exception (ECE) Policy for the Hospital VBP Program

a. Background

(1) Previously Established Extraordinary Circumstance Exception (ECE) Policy Under the Hospital VBP Program

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50704 through 50707) for discussion of our Extraordinary Circumstance Exception (ECE) policy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50704 through 50707), we adopted an ECE policy for the Hospital VBP Program, which recognized that there may be periods of time during which a hospital is affected by an extraordinary circumstance beyond its control. When adopting the policy, we stated that upon a hospital's request, we will consider providing an exception from the Hospital VBP Program requirements to hospitals affected by natural disasters or other extraordinary circumstances (78 FR 50704 through 50706). Specifically, we stated that we interpreted the minimum number of cases and measures requirement in sections 1886(o)(1)(C)(ii)(III) and (IV) of the Act to not include any measures or cases for which a hospital has submitted data during a performance period for which the hospital has been granted a Hospital VBP Program ECE. We expressed belief that this approach would help alleviate the reporting burden for a hospital that is adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the Hospital VBP Program.

On May 8, 2020, we published an Interim Final Rule with public comment (IFC) titled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' in response to the PHE for COVID–19

(hereafter referred to as the ''May 2020 IFC'') (85 FR 27550), where we modified the Hospital VBP Program's ECE policy to allow us to grant ECE exceptions to hospitals which have not requested them when we determine that an extraordinary circumstance that is out of their control, such as an act of nature (for example, a hurricane) or PHE (for example, the COVID–19 pandemic), affects an entire region or locale, in addition to retaining the individual ECE request policy (85 FR 27597 through 27598). We stated that if we grant an ECE to hospitals located in an entire region or locale under this revised policy and, as a result of granting that ECE, one or more hospitals located in that region or locale does not report the minimum number of cases and measures required to enable us to calculate a TPS for that hospital for the applicable program year, the hospital will be excluded from the Hospital VBP Program for the applicable program year. We also stated that a hospital that does not report the minimum number of cases or measures for a program year will not receive a two percent reduction to its base operating diagnosis-related group (DRG) payment amount for each discharge in the applicable program year and will also not be eligible to receive any value-based incentive payments for the applicable program year. We refer readers to sections V.H.6.d. and V.H.6.e. of this final rule for the minimum number of measures and cases that we currently require hospitals to report in order to receive a TPS for a program year under the Hospital VBP Program.

In the May 2020 IFC, we welcomed public comments on our policy to modify the Hospital VBP Program's ECE policy to allow us to grant ECE exceptions to hospitals which have not requested them when we determine that an extraordinary circumstance that is out of their control.

Comment: Some commenters supported CMS in updating the Hospital VBP Program ECE policy to grant ECEs to hospitals which have not requested them. A few commenters noted that they appreciate CMS moving toward consistency of ECE policies across hospital reporting and performance programs. A commenter appreciated that this updated ECE policy helps alleviate the burden to hospital administration in filing an individual ECE request.

Response: We thank commenters for their support and agree that it is important to align with other reporting and performance programs where possible. We also agree that our updated Hospital VBP Program ECE policy will help alleviate burden for providers in future extraordinary circumstances.

As established in the May 2020 IFC, we have finalized our updated ECE policy for the Hospital VBP Program.

(2) Extraordinary Circumstance Exception (ECE) Granted in Response to the PHE for COVID–19

On March 22, 2020, in response to COVID–19, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and VBP programs.[789] Specifically, we announced that we were granting ECEs for certain data reporting requirements and submission deadlines for the first and second quarters of CY 2020. On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare quality reporting and VBP program.[790] For the Hospital VBP Program, we stated that qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication, mortality, and CMS PSI 90 measures. The ECEs also relieved providers and facilities of their obligation to report HCAHPS survey data and CDC NHSN HAI data for the fourth quarter calendar year (CY) 2019, first quarter CY 2020, and second quarter CY 2020.

Because the May 2020 IFC was published after these exceptions were granted, we also clarified the specific guidance and exceptions for the Hospital VBP Program in that IFC. We welcomed public comment on these exceptions granted in response to the COVID–19 PHE.

Comment: A few commenters urged CMS to extend the ECE granted in response to the COVID–19 PHE for the remainder of 2020 in future rulemaking, and a few commenters urged CMS to suspend its hospital quality performance programs or hold hospitals harmless under these programs during the PHE.

Response: We refer readers to section V.H.1. of this final rule for our finalized flexibilities in response to the COVID–19 PHE. We note that while we did not extend the ECE we granted in response to the COVID–19 PHE, we are finalizing in this final rule a number of other policies, including measure suppressions and a special scoring and payment policy for FY 2022, which are intended to mitigate any negative impacts of the COVID–19 PHE on hospitals participating in the Hospital VBP Program.

Comment: A commenter recommended that CMS maintain clear communication with hospitals to avoid duplicative filing.

Response: We believe the policies finalized in this final rule will clearly communicate the Hospital VBP Program's FY 2022 requirements. We also refer readers to *QualityNet.cms.gov* for additional resources. Readers may also sign up for email updates on *QualityNet.cms.gov/listserv-signup* to receive news, information, announcements, and educational offerings/events regarding the Hospital VBP Program

Comment: A few commenters noted that, despite CMS excepting requirements for NHSN reporting of HAI measures for Q4 of CY 2019 and Q1 and Q2 of CY 2020, state regulations may continue to require this reporting. These commenters were concerned that hospitals located in these states would be unable to voluntarily withhold reporting and that their performance on these measures will be scored under the Hospital VBP and HAC Reduction Programs, which may cause bias in the scoring if hospitals in other states do not report on these measures during the impacted reporting periods.

Response: We refer readers to section V.H.1. of the final rule, where we finalize our proposal to suppress seven Hospital VBP Program measures for FY 2022, including the five NHSN HAI measures, as well as our proposal to assign each hospital a value-based incentive payment percentage that results in a value-based incentive payment amount that matches the 2 percent reduction to the base operating DRG payment amount. The net result of these payment adjustments would be neutral for hospitals and a hospital's base operating DRG payment amount would remain unchanged for FY 2022. Therefore, the NHSN HAI data for hospitals in states that requires reporting of the NHSN HAI measures will not negatively impact their scores or payment for FY 2022. We also refer

[789] CMS, Press Release, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID-19 (Mar. 22, 2020), *https://www.cms.gov/newsroom/press-releases/cms-anounces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[790] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Impatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID-19 (Mar. 27, 2020), *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs-pdf.*

readers to section IX.I.3.d. of this final rule where we are finalizing the suppression of third and fourth quarters of CY 2020 (that is, July 1, 2020 through September 30, 2020 (Q3 2020) and October 1, 2020 through December 31, 2020 (Q4 2020)) CDC NHSN HAI and CMS PSI 90 data from the HAC Reduction Program's performance calculations for FY 2022 and FY 2023.

Comment: A commenter requested that CMS consider publishing a clarification to the Hospital VBP Program ECE policy. Specifically, this commenter sought clarification on whether all hospitals will be excluded from the Hospital VBP Program for FY 2022 and FY 2023.

Response: We refer readers to the September 2020 IFC as well as section V.H.7. of this final rule for clarifications on the application of the ECE granted in response to the COVID–19 PHE and additional finalized policies that suppress several measures in the Hospital VBP Program and result in neutral payment adjustments for all hospitals participating in the Hospital VBP Program for FY 2022. We note that we have finalized the suppression of one measure for the FY 2023 Program, and we will continue to evaluate the impact of COVID–19 on the Hospital VBP Program measures to determine the best approach for scoring and payment in FY 2023.

As established in the May 2020 IFC, we have finalized exceptions for qualifying claims for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication, mortality, and CMS PSI 90 measures as well as provider obligations to report HCAHPS survey data and CDC NHSN HAI data for the fourth quarter calendar year (CY) 2019, first quarter CY 2020, and second quarter CY 2020.

(3) Updated Application of the ECE Granted in Response to the PHE for COVID–19

On September 2, 2020, we published a separate IFC, titled ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (hereafter referred to as the ''September 2020 IFC'') (85 FR 54820). The September 2020 IFC updated the ECE we granted in response to the PHE for COVID–19, for the Hospital VBP Program and several other quality reporting programs (85 FR 54827 through 54838).

In the September 2020 IFC, we updated the ECE that we granted for the Hospital VBP Program (85 FR 54833 through 54835) and stated that we will not use any first or second quarter CY 2020 measure data that was voluntarily submitted for scoring purposes under the Hospital VBP Program. We expressed concern with the national comparability of the Hospital VBP Program data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19.

In the September 2020 IFC, we welcomed public comments on our policy to not use any first or second quarter CY 2020 measure data that was voluntarily submitted for scoring purposes under the Hospital VBP Program. We stated that we would respond to those public comments in the FY 2022 IPPS/LTCH PPS final rule. We received some general comments that applied to the Hospital VBP, HAC Reduction, and Hospital Readmissions Reduction Programs:

Comment: Several commenters supported CMS' general updated application of the ECE granted in response to the COVID–19 PHE. A few commenters also agreed with CMS' concerns regarding the national comparability of data from Q1 and Q2 of CY 2020 and noted that the integrity and validity of any measurement calculations associated with this data could be compromised. A commenter encouraged CMS to continue accepting data for purposes of evaluating the impact of COVID–19 on hospitals' outcomes.

Response: We thank commenters for their support.

Comment: A commenter encouraged CMS to consider excluding the remainder of CY 2020 data from use in payment determinations.

Response: We thank commenter for this feedback. Although we are not expanding the ECE we granted in response to the COVID–19 to except submission requirements for the remainder of CY 2020 data from use in our VBP programs, we refer readers to our measure suppression policy and the Hospital VBP Program's special scoring and payment policy for FY 2022 in sections V.H.1., V.H.2 and V.H.6.a of this final rule for further discussion of policies that we are adopting in response to the impact of the COVID–19 PHE on measure data used in payment determinations.

We also received one comment specifically aimed at the policies established for the Hospital VBP Program.

Comment: A commenter supported CMS' revised application of the ECE granted for the COVID–19 PHE for the Hospital VBP Program. This commenter noted its appreciation for CMS' clarification of how it plans to use reported data for future program years.

Response: We thank this commenter for its support.

As established in the September 2020 IFC, we have finalized our updated application of the ECE granted in response to the COVID–19 PHE.

8. Provision To Revise Existing Code of Federal Regulations (CFR) Language by Replacing the Term ''System Administrator'' With the Term ''Security Official''

We proposed to replace the term ''QualityNet System Administrator'' with ''QualityNet security official'' in § 412.167(b)(5) of our regulations. This update will align the terminology used for this program with the terminology we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25495) to use for the Hospital IQR Program. This official is one of hospital's contact people for purposes of the appeal process under § 412.167(b).

We welcomed public comment on this proposal to replace the term ''QualityNet System Administrator'' with ''QualityNet security official'' in our regulation text.

We did not receive public comments and are finalizing this policy to replace the term ''QualityNet System Administrator'' with ''QualityNet security official'' at § 412.167(b)(5) as proposed.

9. Provision To Update References to QualityNet and Hospital Compare for the Hospital VBP Program

There are currently several codified requirements for the Hospital VBP Program in our regulations. However, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25495), we proposed to update regulation text to reflect changes made to CMS resources. Specifically, we proposed to revise regulations in two places:

- At 42 CFR 412.163 in paragraph (d) and at 42 CFR 412.164 at paragraph (b) to update the text to indicate that the *Hospital Compare* website is now available on the Care Compare site at: *https://www.medicare.gov/care-compare*.
- At 42 CFR 412.165 in paragraphs (c)(2) and (c)(4) to update the URL for our QualityNet website from QualityNet.org to *QualityNet.cms.gov.* We note that we launched the redesigned QualityNet website in November 2020.

We welcomed public comment on this proposal to update references to CMS resources in our regulation text.

We did not receive public comments and are finalizing our proposal to update references to CMS resources in our regulation text at § 412.163(d), § 412.164(b), and § 412.165(c)(2) and (c)(4) as proposed.

10. Overall Hospital Quality Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Ratings (Overall Star Ratings). The Overall Star Ratings utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital VBP Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule for details (85 FR 86193 through 86236).

11. References to Additional Requests for Information

We refer readers to section IX.A. of this final rule, which describes our request for information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard. We also refer readers to section IX.B. of this final rule, which describes our request for information on our Equity Plan for Improving Quality in Medicare, which outlines our commitment to closing the health equity gap through improved data collection to better measure and analyze disparities across programs and policies.

I. Hospital-Acquired Condition (HAC) Reduction Program: Updates and Changes (42 CFR 412.170)

1. Regulatory Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program and to the same final rule (78 FR 50708 through 50709) for a detailed discussion of the statutory basis for the Program. For additional descriptions of our previously finalized policies for the HAC Reduction Program, we also refer readers to the following final rules:

- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42402 through 42411); and
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58860 through 58865).

We have also codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

2. Overview of Updates to the HAC Reduction Program and Requests for Information

In section IX.I.3.c. of the proposed rule, we proposed to adopt a cross-program measure suppression policy (86 FR 25497 through 25499) and in section IX.I.3.d. of the proposed rule we proposed to suppress third and fourth quarter CY 2020 CMS PSI 90 and CDC NHSN HAI measure data from the HAC Reduction Program (86 FR 25499 through 25500). In section IX.I.7. of the proposed rule, we clarified some aspects of the Extraordinary Circumstances Exception (ECE) policy (86 FR 25501 through 25502). In section IX.I.9. of the proposed rule, we proposed to revise our regulations for the HAC Reduction Program at 42 CFR 412.172(f)(4) to add the phrase ''or successor website'' to reflect the change in the CMS website name from *Hospital Compare* to *Care Compare* (86 FR 25502).

We also refer readers to section IX.B. of the proposed rule (86 FR 25554 through 25561) and of this final rule, Closing the Health Equity Gap in CMS Quality Programs—A Request for Information, where we requested information on our Equity Plan for Improving Quality in Medicare, which sets out our commitment to closing the health equity gap through improved data collection to better measure and analyze disparities across programs and policies. The request for information asks for public comment regarding the potential stratification of quality measure results by race and ethnicity and the potential creation of a hospital equity score in CMS quality reporting and value-based purchasing programs, including the HAC Reduction Program.

We also refer readers to section IX.A. of the proposed rule (86 FR 25549 through 25554) and of this final rule, where we requested information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard (as described in that section). This request for information supports our goal of moving fully to digital quality measurement in CMS quality reporting and value-based purchasing programs, including the HAC Reduction Program, by 2025.

3. Measures for FY 2022 and Subsequent Years

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41474) for more information about how the HAC Reduction Program supports our goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework.

a. Current Measures

The HAC Reduction Program has adopted six measures to date. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of five CDC NHSN HAI measures: (1) CAUTI; (2) CDI; (3) CLABSI; (4) Colon and Abdominal Hysterectomy SSI; and (5) MRSA bacteremia. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57014), we finalized the use of the CMS PSI 90 measure. These previously finalized measures, with their full measure names, are shown in this table.

HAC Reduction Program Measures for FY 2021 and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
CMS PSI 90	CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716

Technical specifications for the CMS PSI 90 measure can be found on the *QualityNet* website at: *https://qualitynet.cms.gov/inpatient/measures/psi/resources*. Technical specifications for the CDC NHSN HAI measures can be found at CDC's NHSN website at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both websites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In the proposed rule, we did not propose to add or remove any measures.

b. Measure Removal Factors Policy

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42404 through 42406) for information about our measure removal and retention factors for the HAC Reduction Program. In the proposed rule, we did not propose any measure removal and retention factor policy changes.

c. Flexibility for Changes That Affect Quality Measures During a Performance or Measurement Period in the HAC Reduction Program

In previous rules, we have identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating facilities' or practitioners' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 public health emergency (PHE), which has had, and continues to have, significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 pandemic and associated PHE impedes effective quality measurement in many ways. Changes to clinical practices to accommodate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data used in quality measurement and the resulting quality scores. New clinical guidelines, diagnosis or procedure codes, and medications take time to be incorporated into quality measures, and once incorporated, those changes affect measure calculations. Additionally, COVID–19 prevalence is not identical across the country, meaning that the medical provider community has been affected differently at different times throughout the calendar year. Under those circumstances, we remain significantly concerned that quality measurement is distorted, which would result in skewed payment incentives and inequitable payments, particularly for hospitals or other providers that have treated more COVID–19 patients than others.

It is not our intention to penalize hospitals for performance on measures that are affected significantly by global events like the COVID–19 PHE. As previously discussed, the COVID–19 PHE had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including those that may result in HACs as measured by the HAC Reduction Program. As a result of the PHE, hospitals could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, lower payment adjustments in the HAC Reduction Program. We are also concerned that regional and temporal differences in COVID–19 prevalence during the FY 2022, FY 2023, and FY 2024[791] performance periods, which include data collected during the PHE, may directly affect hospitals' HAC measure performance for the FY 2022, FY 2023, and FY 2024 program years. Although these regional and temporal differences in COVID–19 prevalence rates do not reflect differences in the quality of care furnished by hospitals, they directly affect the value-based payment adjustments that these hospitals are eligible to receive and could result in an unfair and inequitable distribution of those assessment of penalties for excess hospital acquired conditions. These inequities could be especially pronounced for hospitals that have treated a large number of COVID–19 patients.

Therefore, we proposed to adopt a policy for the duration of the PHE for COVID–19 that would enable us to suppress a number of measures from the FY 2022 and FY 2023 Total HAC Score calculations for the HAC Reduction Program if we determine that circumstances caused by the PHE for COVID–19 have affected these measures and the resulting Total HAC Scores significantly (86 FR 25497 through

[791] In the proposed rule, we referred only to the FY 2022 and FY 2023 performance periods (86 FR 25497). However, as discussed further in this final rule, we believe that the suppression of third and fourth quarter CY 2020 data from FY 2024 HAC Reduction Program is a logical outgrowth from our proposal to suppress such quarters and comments received from the public.

25499). Under the proposed policy, if we determine that the suppression of a HAC Reduction Program measure is warranted for a program year, we would propose to calculate measure rates for that program year but then suppress the use of those rates to generate Total HAC Scores. We would instead assign each hospital a zero percent weight for any suppressed measures in the Total HAC Score calculation. In the proposed rule, we stated that we would also provide confidential feedback reports to hospitals on their FY 2022, FY 2023, and FY 2024 performance to ensure that they are made aware of the changes in performance rates that we have observed. For CMS NHSN HAI measures, feedback regarding the suppressed data will be provided within NHSN. For the CMS PSI 90 measures, feedback regarding the suppressed data will be provided in public reporting CMS PSI 90 hospital-specific reports (HSRs) prior to publication. We would also publicly report the FY 2022, FY 2023, and FY 2024 data with appropriate caveats noting the limitations of the data due to the PHE for COVID–19, on the Provider Data Catalog, available at *https://data.cms.gov/provider-data/*. Data from Q3 and Q4 CY 2020 will be included in public reporting on *Care Compare* and will also include appropriate caveats.

In developing this proposed policy, we considered what circumstances caused by the PHE for COVID–19 would affect a quality measure significantly enough to warrant its suppression in a value-based purchasing program. We stated our belief that significant deviation in measured performance that can be reasonably attributed to a PHE is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we stated our belief that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 PHE, we stated our belief that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also noted that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new disease or conditions. Finally, we stated our belief that, as evidenced during the COVID–19 PHE, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or facility-level case mix may result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress HAC Reduction Program measures for one or more program years that overlap with the PHE for COVID–19. We proposed to adopt these Measure Suppression Factors for use in the HAC Reduction Program, and for consistency, the following other value-based purchasing programs: Hospital Value-Based Purchasing, Hospital Readmissions Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and End-Stage Renal Disease Quality Incentive Program. We stated our belief that these Measure Suppression Factors will help us evaluate the HAC Reduction Program's measures and that their adoption in the other value-based purchasing programs, as previously noted, will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are as follows:

- Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.
- Rapid or unprecedented changes in—

++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

++ The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

- Significant national shortages or rapid or unprecedented changes in—

++ Healthcare personnel;

++ Medical supplies, equipment, or diagnostic tools or materials; or

++ Patient case volumes or facility-level case mix.

We also considered alternatives to this proposed policy that could fulfill our objective to not hold facilities accountable for distorted measure results under the FY 2022 and FY 2023 Programs. As previously noted, the country continues to grapple with the effects of the COVID–19 PHE, and in March 2020, CMS issued a nationwide, blanket ECE for all hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the COVID–19 PHE. This blanket ECE waived all data reporting requirements for Q1 and Q2 2020 data, including waiving the use of claims data and data collected through the CDC's web-based surveillance system for this data period. Quality data collection resumed on July 1, 2020. This blanket ECE is likely to affect our quality programs significantly, especially in future years as CY 2020 measurement forms the basis for performance assessments in our value-based purchasing programs. We considered extending the blanket ECE that we issued for Q1 and Q2 2020 for Q3 and Q4 2020. This alternative would protect providers and suppliers from having their quality data used for quality scoring purposes while those data are likely to have been affected significantly by the PHE for COVID–19. However, this option would leave no comprehensive data available for us to provide confidential performance feedback to providers nor for monitoring and to inform decision-making for potential future programmatic changes, particularly as the PHE is extended.

As an alternative to the proposed quality measure suppression policy, we also considered not making any further changes to the Program or measures and using Q3 and Q4 2020 quality measurement data that we previously specified for the HAC Reduction Program. However, this alternative would mean assessing hospitals and other providers and suppliers using quality measure data that could be affected significantly by the COVID–19 PHE. Additionally, given the geographic disparities in the COVID–19 PHE's effects, we stated in the proposed rule that we believed that implementation of the FY 2022, FY 2023, and FY 2024 HAC Reduction Programs as previously finalized would place hospitals in regions that were more heavily affected by the pandemic in Q3 and Q4 of 2020 at a disadvantage compared to hospitals in regions that were more heavily affected during the first two quarters of CY 2020, for which we are not using HAC Reduction Program data to calculate the Program's measures.

We stated in the proposed rule that we view this measure suppression proposal as necessary to ensure that the FY 2022 and FY 2023 HAC Reduction Programs do not reward or penalize facilities based on factors that the Program's measures were not designed to accommodate. We intended for this proposed policy to provide short-term

relief to hospitals when we have determined that one or more of the Measure Suppression Factors warrants the suppression of one or more of the HAC Reduction Program's measures.

We invited public comments on this proposal for the adoption of a measure suppression policy for the FY 2022 and FY 2023 HAC Reduction Program years, as previously described, and also on the proposed Measure Suppression Factors that we developed for purposes of this proposed policy. As discussed further in the following subsection of this final rule, we note that our proposal to suppress Q3 and Q4 CY 2020 data also impacts the applicable period for the CMS PSI 90 measure in the FY 2024 HAC Reduction Program. We believe that the suppression of Q3 and Q4 CY 2020 from the FY 2024 HAC Reduction Program is a logical outgrowth of the proposal to suppress such quarters from the Program and comments received from the public.

We also invited comment on whether we should consider adopting a measure suppression policy that would apply in a future national PHE, and if so, whether under such a policy, we should have the flexibility to suppress certain measures without specifically proposing to do so in rulemaking. We also requested comment on whether we should in future years consider adopting any form of regional adjustment for the proposed measure suppression policy that could take into account any disparate effects of circumstances affecting hospitals around the country that would prompt us to suppress a measure. For example, the COVID–19 PHE affected different regions of the country at different rates depending on factors like time of year, geographic density, State and local policies, and health care system capacity. In future years and for future PHEs, should they arise, we also requested commenters' feedback on whether we should, rather than suppress a measure completely, consider a suppression policy with more granular effects based on our assessment of the geographic effects of the circumstances, and if so, how region-based measure suppression could be accounted for within the program's scoring methodology.

The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposed measure suppression policy, agreeing with our stated goal of ensuring that hospitals are not rewarded or penalized for their quality performance based on non-representative data. Some commenters recommended that we ensure that the suppression policy does not unintentionally penalize hospitals.

Response: We thank the commenters for their support. We acknowledge commenters' concern that the suppression policy should not unintentionally penalize hospitals. We note that we proposed the suppression policy due to the impacts of the COVID–19 PHE because of our concern in the ability to make fair, national comparisons of hospitals around the country.

Comment: Some commenters expressed concerns about our proposed suppression policy. Some commenters suggested that we should limit this policy to the current PHE given the unique circumstances involved in the COVID–19 pandemic. A few commenters expressed concerns about CMS being empowered to implement scoring adjustments and payment changes outside of rulemaking, and worried that comparisons between suppressed and unsuppressed scores would be unfair.

Response: We did not propose to apply this policy beyond the COVID–19 PHE. Any scoring adjustments or payment changes that might address a different, future fiscal year of the program due to the COVID–19 PHE or another type of emergency would be proposed through rulemaking. We acknowledge the commenters' concerns about potentially unfair comparisons and will consider for future rulemaking any such issues we identify.

Comment: Several commenters argued that we should not publicly report suppressed data, suggesting that data unfit to determine payments adjustments should not be publicly reported, while others suggested that we should note clearly that any publicly-reported data has been affected by the COVID–19 PHE.

Response: We understand the commenters concern about publicly reporting measure data during the PHE due to COVID–19. However, as noted previously in section IX.I.3.c. of the preamble of this final rule, we will make clear in the public presentation of the data that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the PHE due to COVID–19. Displaying this information will promote transparency on the impacts of the PHE due to COVID–19, and we will appropriately caveat the data in order to mitigate public confusion.

Comment: Several commenters recommended that we study carefully the effects of the measure suppression policy and the measure suppression factors to inform any suppression policies for future PHEs. Several commenters recommended that we work with stakeholders before adopting additional measure suppression policies or any subregulatory policy changes on this topic in the future, including any potential changes to the Measure Suppression Factors, and requested that we explain the effects of any changes to the Suppression Factors in detail. A commenter suggested that we continue monitoring the effects of COVID–19 on 2021 quality performance and consider updating measure specifications to exclude COVID-positive patients or change our risk adjustment models. Other commenters suggested that we monitor the shorter performance periods carefully, as well as the effects of the policy on future benchmarking, and that we assess the indirect effects that the COVID–19 PHE has had on all aspects of medical care delivery.

Response: We share commenters' concerns about the potential long-term effects of the measure suppression policy, including the measure suppression factors. We agree with commenters that we should monitor the PHE's ongoing effects carefully and we will work with measure developers to refine measure specifications as feasible for future rulemaking. We will also assess performance periods, benchmarks, and other effects of the COVID–19 PHE carefully, and we will monitor the policy's effects carefully as we implement it. We welcome stakeholders' continuing feedback as we continue responding to the PHE.

Comment: Some commenters expressed support for the proposed Measure Suppression Factors, while others suggested that we include more flexibility in the Suppression Factors, particularly to account for future PHEs, and that we consult with stakeholders when applying these factors in the future. A commenter recommended that we explicitly include flexibility in our suppression factors to account for our evolving understanding of COVID–19.

Response: We thank the commenters for this feedback. While we appreciate the commenter's suggestion that we incorporate more flexibility into the current Measure Suppression Factors, we believe the specificity with which we proposed them was necessary to provide hospitals, patients/consumers, and other stakeholders with clear insight into the decision-making process that we employed in response to the COVID–19 PHE. However, we will also engage with stakeholders when developing and implementing these Suppression Factors for future PHEs.

Comment: Some commenters recommended that we refine our

proposed Measure Suppression Factors. Some commenters suggested that we define them more precisely to be fully transparent with the factors' terms and effects, arguing that we have not defined what we consider to be ''significant'' deviation in national performance on a measure during a PHE. A commenter also argued that the Suppression Factors should be focused on effects on Medicare beneficiaries, not on providers or circumstances within the control of providers. A commenter suggested that we consider suppressing measures for individual hospitals where performance may have deviated significantly from past performance, while another commenter recommended that we ensure that the Suppression Factors do not assess provider organizations' quality per se, but rather, the PHE at issue.

Response: We thank the commenters for this feedback. We believe that some level of discretion is necessary in the face of evolving circumstances like those that have confronted us in the form of the COVID–19 PHE. In deciding which measures to suppress, and as discussed further in section VI.H.1.b. of this final rule, we examined each measure and determined that the evidence showed deviation in the individual measure performance data associated with the COVID–19 PHE. We believe providing the evidence for the measure suppressions included in this final rule is transparent and provides sufficient explanation for our rationales. We note further that we designed several of the measure suppression factors to account for circumstances that could affect the health and safety of patients and healthcare personnel, and we believe that situations like personal protective equipment (PPE) shortages affect the care provided to Medicare beneficiaries. We recommend that any individual hospitals believing that they have faced extraordinary circumstances that affect their quality performance, but that have not been addressed by the suppression policy, consider seeking an Extraordinary Circumstances Exception.[792]

Comment: Some commenters supported regional adjustments to the measure suppression policy, suggesting that we should account for disparate effects of circumstances like the COVID–19 pandemic around the country. Commenters requested that we seek stakeholders' feedback before adopting more granular suppression policies in the future. A commenter cautioned against regional adjustments, suggesting that such adjustments would not account for differences in PHE prevalence at safety-net hospitals that take on leading roles during PHEs.

Response: We thank the commenters for their feedback and will consider it for future rulemaking. We share the commenter's concern that adjustments to account for regional differences in a PHE's effects may not fully capture those differences.

Comment: Several commenters expressed support for our proposal to provide confidential performance feedback to hospitals on suppressed measures.

Response: We thank the commenters for their support. In the HAC Reduction Program, information regarding performance on CDC NHSN HAI data will be available within NHSN. For the CMS PSI 90 measures, feedback regarding suppressed data will be provided in public reporting CMS PSI 90 HSRs.

After consideration of the public comments we received, we are finalizing our proposal to adopt a measure suppression policy and measure suppression factors described above for the FY 2022, and FY 2023 HAC Reduction Program years, without modification. Further, as discussed above, and as a logical outgrowth of the proposed policy and of public comments, we are finalizing a policy to suppress Q3 and Q4 CY 2020 data from the FY 2024 HAC Reduction Program.

d. Provision To Suppress Third and Fourth Quarter CY 2020 Data From the FY 2022, FY 2023, and FY 2024 HAC Reduction Program [793]

In section IX.I.3.c. of the proposed rule, we proposed to adopt a measure suppression policy (86 FR 25497 through 25499). In section IX.I.3.d. of the proposed rule, we proposed to suppress the third and fourth quarters of CY 2020 (that is, July 1, 2020 through September 30, 2020 (Q3 2020) and October 1, 2020 through December 31, 2020 (Q4 2020)) CDC NHSN HAI and CMS PSI 90 data from our performance calculations for FY 2022 and FY 2023 under the proposed Measure Suppression Factor (1) ''significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years;'' and the Measure Suppression Factor (4) subfactor, ''significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix'' (86 FR 25499 through 25500). Although Q3 and Q4 2020 data would be suppressed from the Total HAC Score calculation, hospitals would still be required to submit such data and such data would be used for public reporting purposes.

The proposal to suppress Q3 and Q4 CY 2020 data also impacts the applicable period for the CMS PSI 90 measure in the FY 2024 HAC Reduction Program. We believe that the suppression of Q3 and Q4 CY 2020 data from the FY 2024 HAC Reduction Program is a logical outgrowth of the proposal to suppress such quarters from the Program and comments received from the public.

As described in more detail in section IX.B.7.a. of this final rule, through memoranda released in March 2020 and an IFC published in September 2020 (85 FR 54827 through 54828), in response to the COVID–19 PHE, we excluded, by application of our ECE policy, all data submitted regarding care provided during the first and second quarters of CY 2020 from our performance calculations for FY 2022 and FY 2023. We excluded such data because of our concerns about the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations, along with different impacts resulting from different State and local laws and policy changes implemented in response to COVID–19.

We continue to be concerned about measure performance and the national comparability of such performance during Q3 and Q4 2020 and therefore proposed to suppress Q3 2020 and Q4 2020 HAI and CMS PSI 90 measure data from the calculation of the Total HAC Score. An analysis performed by the CDC found that CLABSI, CAUTI, and MRSA had statistically significant measure rate increases during Q3 and Q4 CY 2020 as compared to Q3 and Q4 CY 2019. We stated our belief that the measure data may have been distorted due to circumstances unique to the effects of the COVID–19 PHE, such as staffing shortages and turnover, patients that are more susceptible to infections due to increased hospitalization stays, and longer indwelling catheters and central lines. As for the SSI and CDI measures, neither measure had a statistically significant increase or

[792] For more information regarding Extraordinary Circumstances Exceptions requests under the HAC Reduction Program, please see: *https://qualitynet.cms.gov/inpatient/hac/participation#tab2.*

[793] The corresponding section title in the proposed rule did not include FY 2024 (86 FR 25499). However, as discussed further in this final rule, we believe that the suppression of third and fourth quarter CY 2020 data from FY 2024 HAC Reduction Program is a logical outgrowth from our proposal to suppress such quarters and comments received from the public.

decrease during Q3 and Q4 2020 as compared to Q3 and Q4 2019. For the SSI measure, the low reporting volume is due to the decrease in surgeries during the COVID–19 PHE, while the CDI measure has historically been declining. Though the COVID–19 PHE may not have the same clinical impact on the SSI and CDI measures, we stated in the proposed rule that we believe that due to the low reporting volume of these two measures and for maintaining consistency of the full CDC NHSN HAI measure set, all five CDC NHSN HAI measures should be suppressed instead of just three of them. Similarly, our analysis of CMS PSI 90 measure suggested that comparability of performance on the measure has also been impacted by the PHE. Our analysis found a decrease in volume across all component Patient Safety Indicator (PSI) measures, especially those related to elective surgeries (postoperative acute kidney injury rate, postoperative respiratory failure rate, and postoperative sepsis rate). Our analysis also found increased risk-adjusted rates for patients with COVID–19 compared to patients without COVID–19 as well as increased risk-adjusted rates for the three component PSI measures that include non-surgical patients (pressure ulcer rate, iatrogenic pneumothorax rate, and in-hospital fall with hip fracture rate) while the surgical-specific component PSI measures (perioperative hemorrhage and hematoma rate, postoperative acute kidney injury rate, postoperative respiratory failure rate, perioperative pulmonary embolism or deep vein thrombosis rate, postoperative sepsis rate, postoperative wound dehiscence rate, and unrecognized abdominopelvic accidental puncture/laceration rate) did not see substantial change in risk-adjusted rates.

As previously noted, under this policy, participating hospitals would continue to report all HAC Reduction Program measures' data to CMS, and in the case of the CDC NHSN HAI measures, to CDC, so that we can monitor the effect of the circumstances on quality measurement and determine appropriate policies in the future. We would also use Q3 and Q4 2020 data in feedback reports to hospitals as part of program activities, including to inform their quality improvement activities, and to ensure that they are made aware of and have an opportunity to preview the changes in performance rates we observe and display via public reporting to ensure transparency.

The proposed suppression of Q3 and Q4 2020 HAI and CMS PSI 90 measure data would result in the following applicable periods for calculating Total HAC Scores for FY 2022, FY 2023, and FY 2024 HAC Reduction Programs. For the FY 2022 HAC Reduction Program, the applicable period used for scoring for the CMS PSI 90 measure would remain the same as resulted from the previously granted ECE, that is, the 18-month period from July 1, 2018 through December 31, 2019. For the CDC NHSN HAI measures, this further exclusion would result in an applicable period for FY 2022 of the 12-month period from January 1, 2019 through December 31, 2019. For the FY 2023 HAC Reduction Program, the exclusion would result in a shortened applicable period, for the CMS PSI 90 measure, to the 12-month period from July 1, 2019 through December 31, 2019 and January 1, 2021 through June 30, 2021, and for the CDC NHSN HAI measures to the 12-month period from January 1, 2021 through December 31, 2021. For the FY 2024 HAC Reduction Program, the exclusion would result in a shortened applicable period, for the CMS PSI 90 measure, to the 18-month period of January 1, 2021 through June 30, 2022.

We stated our belief that using data from the proposed periods will provide sufficiently reliable data for evaluating hospital performance that we can use for FY 2022, FY 2023, and FY 2024 scoring.[794] In the FY 2017 IPPS/LTCH PPS final rule, we clarified that a hospital has complete data for the CMS PSI 90 measure if it has 12 months or more of data and three or more eligible discharges for at least one component PSI measure within the CMS PSI 90 composite measure (81 FR 57021). Further, as noted in that rule, NQF determined that the CMS PSI 90 measure is reliable using 12 months of data (81 FR 57021). We have also determined that a 12-month performance period provides us with sufficient data on which to score hospital performance on NHSN measures in the Safety domain of the Hospital VBP Program (79 FR 50071). We also noted that 12-month performance periods are consistent with the reporting periods used for these measures under the Hospital VBP Program (79 FR 50071) and when the measures were previously in the Hospital IQR Program (78 FR 50689).

In determining how to address the impact of the COVID–19 PHE on hospital performance and calculating Total HAC Scores for FY 2022 and FY 2023, we also considered as an alternative to suppressing all Q3 and Q4 2020 data, suppressing CDC NHSN HAI measure data while using the CMS PSI 90 measure data. This alternative would have focused on suppressing those measures most impacted by the COVID–19 PHE. An analysis revealed that smaller and rural hospitals would be more negatively impacted by suppressing data for those measures most impacted by the COVID–19 PHE. Additionally, as previously discussed, we still have concerns about the comparability of data for the CMS PSI 90 measure from Q3 and Q4 2020 due to differences in the risk-adjusted rate of component PSI measures for COVID-positive patients.

We also considered making no modifications to the program and suppressing no measure data from Q3 and Q4 2020 for assessing FY 2022 and FY 2023 Total HAC Scores as an additional alternative to using the measure suppression policy. As discussed, when considering this previously discussed approach, this alternative would be operationally easier to implement, but would mean assessing participating hospitals using quality measure data that have been impacted by the COVID–19 PHE without additional adjustments to the measure. Additionally, given the geographic disparities in the COVID–19 PHE's effects, this policy could place hospitals in regions that were hit harder by the pandemic in Q3 and Q4 of 2020 at a disadvantage compared to hospitals in regions that were more heavily affected earlier in CY 2020. Ultimately, we stated our belief that our proposal to suppress both CDC NHSN HAI and CMS PSI 90 measure data from Q3 and Q4 2020 more fairly addresses the impact of the COVID–19 PHE on participating hospitals.

We invited comments on our proposal to suppress third and fourth quarter CY 2020 CDC NHSN HAI and CMS PSI 90 measure data from the HAC Reduction Program.

Comment: Many commenters supported our proposal to suppress third and fourth quarter CY 2020 data from the FY 2022 and FY 2023 HAC Reduction Program.

Response: We thank the commenters for their support.

Comment: A commenter supported the proposal but asked CMS to provide information regarding the number of hospitals likely to be eligible to participate in the program based on the suppression policy.

Response: We thank the commenter for its support. With the suppression of Q3 and Q4 CY 2020 data, an estimated 3,066 hospitals will receive Total HAC

[794] Although the corresponding paragraph in the proposed rule did not include FY 2024 (86 FR 25499), as discussed further in this final rule, we believe that its inclusion is a logical outgrowth of our proposal to suppress Q3 and Q4 CY 2020 data and comments received from the public.

Scores in FY 2022. See Appendix A for additional information regarding the numbers of hospitals estimated to be eligible to participate in the program by type for FY 2022.

Comment: Several commenters supported the proposal to suppress third and fourth quarter CY 2020 data from the HAC Reduction Program and agreed that the data should be suppressed for future performance periods. These commenters also requested that CMS continue to monitor and evaluate available data to determine whether additional quarters of data should be suppressed for future performance periods due to the ongoing impacts of the PHE. These commenters expressed concerns that first and second quarter CY 2021 data may still be affected by the pandemic and using those data may unfairly disadvantage hospitals in certain regions or that serve certain populations. A commenter requested that CMS consider updating measure specifications to exclude patients with primary and secondary diagnoses of COVID–19 from HAC Reduction Program measures or adjust our risk adjustment models to account for prior COVID–19 diagnoses and the impact of COVID–19 on CY 2021 performance. Another commenter requested that CMS clarify how it is considering handling first and second quarter CY 2021 data.

Response: We appreciate commenters' support to suppress third and fourth quarter CY 2020 data from future performance periods. We are suppressing this data from FY 2022 and FY 2023 HAC Reduction Programs, as proposed. We also will suppress the data from FY 2024 HAC Reduction Program as a logical outgrowth from the proposal to suppress such data and comments received from the public. We continue to monitor the impact of the PHE on program data, including on CY 2021 data, and will take commenters' concerns and recommendations under consideration in the future.

Comment: A few commenters supported the proposal to suppress third and fourth quarter CY 2020 data from Total HAC Score calculations, but did not support public reporting of suppressed data, including in Overall Star Ratings. A commenter expressed concern that the current footnote structure on Care Compare is not designed for patient and/or layperson navigation and therefore would be insufficient to communicate the gravity of the impact that the pandemic had on quality measures. A commenter recommended that CMS provide appropriate caveats and education to clarify that publicly reported results are based on data from the PHE. Another commenter expressed concern that the information will not be accurate enough for stakeholder decision making and recommended CMS perform analyses to ensure the reliability and validity of the results of each measure before reporting them publicly. The commenter stated that if the data are used in public reporting, CMS should consider strategies to ensure the accuracy of the information provided to consumers such as using data from before the PHE, excluding data from 2020, and assessing performance changes to ensure new results track with historical performance.

Response: We understand the commenters concern about publicly reporting data during the PHE due to COVID–19. However, we will make clear in the public presentation of the data that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the PHE due to COVID–19. We will appropriately caveat the data in order to mitigate public confusion and avoid misrepresenting quality of care. Four quarters of data will be publicly available on Care Compare, while HAC Reduction Program performance data will be available on the Provider Data Catalog, available at *https://data.cms.gov/provider-data/*. CMS continues to evaluate the data impacts and will provide information on future refreshes of the Overall Hospital Star Ratings when available.

Comment: A few commenters supported our proposal to suppress Q3 and Q4 2020 data from the CDC NHSN HAI measures but raised concerns regarding the suppression of those data from the CMS PSI 90 measure. A few commenters expressed concern as to whether the CMS PSI 90 measure remained reliable with a performance period of 12 months. Other commenters requested that CMS continue to analyze data regarding the reliability of using shortened periods and a commenter requested that CMS make the results of such analysis public.

Response: We appreciate the commenters' feedback. As detailed above, we have concluded that the updated version of the CMS PSI 90 measure currently adopted in the Program remains sufficiently reliable with a performance period of 12 months. As noted above, the proposal to suppress Q3 and Q4 CY 2020 data from the CMS PSI 90 measure impacts FY 2023 and FY 2024. Because the applicable period for FY 2022 would remain the same as resulted from the previously granted ECE (the 18-month period from July 1, 2018 through December 31, 2019) and use only data prior to the PHE, no additional suppression is required for FY 2022.

Comment: A few commenters supported the proposal to suppress Q3 and Q4 CY 2020 data from the Total HAC scores but were concerned that our policy required hospitals that submit such data due to state requirements to also submit an Extraordinary Circumstances Exception (ECE) in order to have the data suppressed. Those commenters urged CMS to adopt a streamlined approach to automatically exclude such data.

Response: We clarify that all subsection (d) hospitals are still required to submit Q3 and Q4 CY 2020 CDC NHSN HAI and CMS PSI 90 data for the HAC Reduction Program. However, all such data will be automatically suppressed from Total HAC Score calculations for FY 2022, FY 2023, and FY 2024 and no ECE is required to suppress those data. If a hospital wishes to request to not submit such data, an ECE would be required.

Comment: A commenter requested that CMS empirically test whether the pandemic significantly changed risk-standardized rates of hospital outcomes, including HACs and patient safety indicators. The commenter requested that CMS specify the statistical methodology used for determining whether circumstances caused by the PHE affected HAC scores. The commenter also suggested that patients and consumers may need relevant information on which hospitals were able to provide high-quality clinical outcomes despite circumstances beyond their control, as this may indicate pre-existing excellence in hospital processes and structures which are known to be associated with better outcomes.

Response: We thank the commenter for its response. As stated in the proposed rule (86 FR 25499), an analysis performed by the CDC found that CLABSI, CAUTI, and MRSA had statistically significant measure rate increases in Q3 and Q4 CY 2020 as compared to Q3 and Q4 CY 2019. Similarly, our analysis of CMS PSI 90 measure suggested that comparability of performance on the measure has also been impacted by the PHE. We agree with the commenter that patients, consumers, and other stakeholders may find information regarding how hospitals performed during the PHE relevant, and that is why we will be using Q3 and Q4 CY 2020 data in public reporting. As we have discussed in response to other comments, we believe that we should be as transparent as possible with the performance information that we collect.

Comment: Several commenters expressed concern that the truncated applicable periods will in effect double-penalize hospitals that were in the worst quartile in FY 2021. Specifically, these commenters are concerned that by reusing only 2019 data, these hospitals may remain in the worst quartile even if they implemented policy and operational changes to improve their performance in 2020.

Response: We appreciate commenters' concern. Since publication of the proposed rule, we have analyzed the removal of CY 2020 data from the FY 2022 HAC Reduction Program and found a change in worst-performing quartile status for 17.2 percent of hospitals relative to their FY 2021 worst-performing quartile status, with 8.6 percent moving into the worst-performing quartile and 8.6 percent moving out, which is consistent with the proportion of hospitals that change their worst-performing quartile status in previous years. We therefore do not believe that hospitals will be unfairly double penalized due to the suppression of data. We refer readers to Appendix A for additional information regarding the estimated numbers of hospitals in the worst-performing quartile by hospital characteristic for FY 2022.

Comment: A commenter did not support the proposal to suppress Q3 and Q4 CY 2020 data and recommended that CMS risk-adjust for COVID–19 as a patient-level risk factor instead. The commenter expressed concerns that having a 12-month applicable period and an overlapping 18-month applicable period for CMS PSI 90 used in *Care Compare* at the same time would cause confusion and that risk-adjusting would allow for the same length of applicable period. Some commenters also recommended that CMS consider excluding COVID–19 patients from the CMS PSI 90 measure calculations instead of suppressing the measure.

Response: We appreciate the commenter's feedback. In determining how to address the impact of the COVID–19 PHE on hospital performance and calculating Total HAC Scores for FY 2022, FY 2023, and FY 2024, we considered risk-adjusting for COVID–19 as a patient-level risk factor. We ultimately determined that the measure suppression policy was preferable due to implementation concerns associated with making substantive changes to quality measure specifications that would necessitate NQF approval and rulemaking. We will continue to consider the best treatment of the CMS PSI 90 measure and monitor the data, and may revisit this approach in future rulemaking for future fiscal years. We will include appropriate information and caveats when publicly reporting the resulting performance data.

Comment: A commenter stated its belief that CMS' proposal to suppress two quarters of data indicated that CMS can exempt certain hospitals from HAC Reduction Program calculations. This commenter specifically believed that Indian health providers are at an unfair disadvantage under the HAC Program and should be exempted from the program's calculations.

Response: We appreciate and share the commenter's concerns regarding the impact of the COVID–19 PHE on Indian health providers. Under section 1886(p) of the Act, we are required to include all subsection (d) hospitals in the HAC Reduction Program unless exempt per section 1886(p)(2)(C) of the Act. We note that the measure suppression policy we are finalizing and its application to the HAC Reduction Program to suppress Q3 and Q4 CY 2020 data from Total HAC Score calculations is intended to be a limited approach to address in the short-term the COVID–19 PHE, which was an unanticipated event on a national and global scale. The focus of the measure suppression policy is to address the impact of the COVID–19 PHE on the quality measure data and the national comparability of such data, but it does not change hospital eligibility and participation requirements of the Program. Regarding the performance of Indian health providers under the HAC Program, we take the commenter's concerns seriously and will take them into consideration as we continue to monitor the impact of the program on various types of hospitals.

Comment: A few commenters did not support the proposal to suppress Q3 and Q4 CY 2020 data and requested that CMS not enforce the one-percent payment reduction for FY 2022 because reliable comparisons cannot be made due to the PHE.

Response: We appreciate commenters concerns. However, under section 1886(p) of the Act, we are required to impose a 1-percent payment reduction on the quartile of subsection (d) hospitals with the highest Total HAC Scores. As discussed in this section and section I.3.c., we considered various options for accounting for the impact of the PHE, and we believe that the measure suppression policy is the best solution with the data available that balances maintaining the HAC Reduction Program to continue incentivizing quality of care related to patient safety and adverse events while addressing the immediate impact of the COVID–19 PHE on the national comparability and reliability of the data that are used in the Program.

After consideration of the public comments we received, we are finalizing our proposal to suppress Q3 and Q4 CY 2020 data from the FY 2022 and FY 2023 HAC Reduction Programs, without modification. Further, as discussed above, and as a logical outgrowth of the proposed policy and of public comments, we are finalizing a policy to suppress Q3 and Q4 CY 2020 data from the FY 2024 HAC Reduction Program.

4. HAC Reduction Program Scoring Methodology and Scoring Review and Corrections Period

In FY 2019 IPPS/LTCH PPS final rule (83 FR 41484 through 41489), we adopted the Equal Measure Weights approach to scoring and clarified the Scoring Calculations Review and Correction Period (83 FR 41484) for the HAC Reduction Program. Hospitals must register for a *QualityNet* website's secure portal account in order to access their annual hospital-specific reports. We will continue using this scoring methodology and the Scoring Calculations Review and Correction Period process in FY 2021 and for subsequent years. In the proposed rule, we did not propose any changes to the HAC Reduction Program scoring methodology or Scoring Calculations Review and Corrections Period.

5. Validation of HAC Reduction Program Data

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we adopted processes to validate the CDC NHSN HAI measure data used in the HAC Reduction Program, because the Hospital IQR Program finalized its proposals to remove CDC NHSN HAI measures from its program. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42406 through 42410), we provided additional clarification to the validation selection and scoring methodology. We also refer readers to the *QualityNet* website for more information regarding chart-abstracted data validation of measures. In the FY 2020 IPPS/LTCH PPS final rule (85 FR 58862 through 58865), we finalized our policy to align the HAC Reduction Program validation process with that of the Hospital IQR Program. Specifically, we aligned the hospital selection and submission quarters beginning with FY 2024 Hospital IQR and HAC Reduction Programs validation so that we only require one pool of hospitals to submit data for validation. Additionally, we finalized a policy requiring hospitals to submit digital files when submitting

medical records for validation of HAC Reduction Program measures, for the FY 2024 program year and subsequent years.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58862 through 58865), we finalized our policy that for the FY 2024 program year and subsequent years, we will use measure data from all of CY 2021 for both the HAC Reduction Program and the Hospital IQR Program, which must be reported using the following validation schedule.

Finalized Validation Period for the HAC Reduction Program in FY 2024
[*Dates are subject to change]

Discharge Quarters by Fiscal Year (FY)	Current CDC NHSN HAI Submission Deadline*	Current CDC NHSN HAI Validation Templates*	Estimated CDAC[795] Record Request	Estimated Date Records Due to CDAC	Estimated Validation Completion
Q1 2021	08/15/2021	08/01/2021	08/30/2021	09/29/2021	12/15/2021
Q2 2021	11/15/2021	11/01/2021	11/29/2021	12/29/2021	03/15/2022
Q3 2021	02/15/2022	02/01/2022	02/28/2022	03/30/2022	06/15/2022
Q4 2021	05/15/2022	05/01/2022	05/30/2022	06/29/2022	09/15/2022

We did not propose any changes to the policies regarding measure validation in the proposed rule.

6. Overall Hospital Quality Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Ratings (Overall Star Ratings). The Overall Star Ratings utilizes data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the HAC Reduction Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule for details. We did not propose any changes to this policy in the proposed rule.

7. Extraordinary Circumstances Exception (ECE) Policy for the HAC Reduction Program

a. Background

(1) Previously Established Extraordinary Circumstance Exception (ECE) Policy Under the HAC Reduction Program

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581) and the FY 2018 IPPS/LTCH PPS (82 FR 38276 through 38277) for discussion of our Extraordinary Circumstances Exception (ECE) policy. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581), we adopted an ECE policy for the HAC Reduction Program, which recognized that there may be periods of time during which a hospital is affected by an extraordinary circumstance beyond its control. When adopting the policy, we noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's measure results or Total HAC Score for the applicable performance period. By minimizing the data excluded from the program, the policy enabled affected hospitals to continue to participate in the HAC Reduction Program for a given fiscal year if they otherwise continued to meet applicable measure minimum threshold requirements. We expressed the belief that this approach would help alleviate the burden for a hospital that might be adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the HAC Reduction Program. In developing this policy, we considered a policy and process similar to that for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended § 412.40(c)(2)) to refer to ''extension or exemption'' instead of the former ''extension or waiver''). We also considered how best to align an extraordinary circumstance exception policy for the HAC Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital Value-Based Purchasing (VBP) Program, to the extent feasible.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38276 through 38277), we modified the requirements for the HAC Reduction Program ECE policy to further align with the process used by other quality reporting and value-based purchasing programs for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control.

(2) Extraordinary Circumstances Exception (ECE) Granted in Response to the COVID–19 Public Health Emergency

On March 22, 2020, in response to COVID–19, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs.[796] Specifically, we announced that we were granting ECEs for certain data reporting requirements and submission deadlines for the first and second quarters of CY 2020. On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare quality reporting and value-based purchasing program.[797] In that memorandum, we stated that qualifying

[795] The CMS Clinical Data Abstraction Center (CDAC) performs the validation.

[796] CMS, Press Release, CMS Annouces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19 (Mar. 22, 2020), *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[797] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Rental Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

claims would be excluded from the measure calculations for the CMS PSI 90 for the first and second quarters of calendar year (CY) 2020. The ECEs also relieved providers and facilities of their obligation to report CDC NHSN HAI data for the fourth quarter CY 2019, first quarter CY 2020 and second quarter CY 2020.

(3) Updated Application of the ECE Granted in Response to the COVID–19 PHE

On September 2, 2020, we published the interim final rule with comment period (IFC) titled ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820). The IFC updated the ECE we granted in response to the PHE for COVID–19, for the HAC Reduction Program and several other quality reporting programs (85 FR 54827 through 54838).

In the IFC, we updated the previously announced application of our ECE policy for the HAC Reduction Program (85 FR 54830 through 54832) to the COVID–19 PHE to exclude any CDC NHSN HAI data submitted regarding care provided during first and second quarter of CY 2020 from our calculation of performance for FY 2022 and FY 2023, even if optionally reported. We recognized that the chart-abstracted measures in the HAC Reduction Program are calculated based on data submitted to the CDC's NHSN and that because the CDC uses the same data for epidemiological surveillance, hospitals may have reporting requirements which are not affected by our ECE (for example, State requirements). We expressed concern with the national comparability of the HAC Reduction Program data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19.

In the IFC, we welcomed public comments on our policy to exclude any data submitted regarding care provided during the first and second quarter of CY 2020 from our calculation of performance for the FY 2022 and FY 2023 program years.

In the September 2, 2020 IFC, we also announced that if due to ECEs related to the COVID–19 PHE, we do not have enough data to reliably measure national performance, we may propose to not score hospitals based on such limited data or make the associated payment adjustments to hospitals under the IPPS for the affected program year. We stated that, if circumstances warranted, we could propose to suspend prospective application of program penalties or payment adjustments through the annual IPPS/LTCH PPS proposed rule. We also stated that, in the interest of time and transparency, we may provide subregulatory advance notice of our intentions to suspend such penalties and adjustments through routine communication channels to facilities, vendors, and QIOs. The communications could include memos, emails, and notices on the public QualityNet website (*https://www.qualitynet.cms.gov/*).[798]

We received the following comments on the IFC.

Comment: A commenter supported our policy to exclude any data submitted regarding care provided during the first and second quarter of CY 2020 from our calculation of performance for the FY 2022 and FY 2023 program years and expressed agreement that data should not be utilized if hospital performance cannot be appropriately compared.

Response: We thank the commenter for the support.

Comment: A commenter did not support scoring optionally submitted CY 2019 fourth quarter data. The commenter argued that hospitals have faced significant financial challenges during the pandemic and that the decision to use the data, which were submitted by over 95 percent of hospitals, created additional uncertainty for hospitals because it is difficult for them to anticipate a payment reduction with nearly 5 percent of hospitals not reporting data. The commenter concluded that given the financial toll of the pandemic, CMS should refrain from imposing the 1-percent payment reduction under the HAC Reduction Program.

Response: We believe that because nearly all hospitals reported their Q4 2019 HAI data by the submission deadline and reporting rates for the quarter were similar to quarters prior to the PHE, the optional reporting for the relatively small number of hospitals that needed the flexibility at the beginning of the PHE did not create additional uncertainty for hospitals. We do not have concerns about the validity or reliability of the Q4 2019 reported data that reflects performance on a time period before the COVID–19 PHE. Additionally, although we appreciate the financial toll of the pandemic on hospitals, under section 1886(p)(1) of the Act, we are statutorily required to impose a 1-percent payment reduction to the worst-performing quartile of all subsection (d) hospitals.

In the IFC, we finalized the exclusion of any data submitted regarding care provided during the first and second quarter of CY 2020 from our calculation of performance for the FY 2022 and FY 2023 program years. We noted that the inclusion of data optionally reported by hospitals for the fourth quarter of CY 2019 in calculating hospitals' Total HAC Scores was consistent with the policy stated in the March 27, 2020 guidance memo.

In section IX.I.3.d. of this final rule, we finalized our policy to suppress third and fourth quarter CY 2020 data from FY 2022, FY 2023, and FY 2024 Total HAC Scores using the measure suppression policy.

b. General Clarifications to HAC Reduction Program ECE Policy

After the nationwide ECE granted in response to the COVID–19 PHE ended, we received several requests from hospitals for individual ECEs under the HAC Reduction Program, due to extraordinary circumstances resulting from the continuing impact of the pandemic. These individual ECE requests specifically requested clarity on whether CDC NHSN HAI measure data that hospitals submitted to the CDC NHSN because of State reporting requirements could be excluded from the HAC Reduction Program Total HAC Score calculations. In this final rule, we would like to clarify that an ECE granted under the HAC Reduction Program may allow an exception from quality data reporting requirements and/or may grant a request to exclude any data submitted (whether submitted for claims purposes or to the CDC NHSN) from the calculation of a hospital's measure results or Total HAC Score for the applicable period, depending on the exact circumstances under which the request was made.

We have also received a few ECE requests from hospitals for an exception from the HAC Reduction Program payment reduction. The ECE policy for the HAC Reduction Program is intended to provide relief for a hospital that has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the hospital's control by excluding data and/or granting an exception with respect to data reporting requirements for the

[798] We note that the QualityNet website (previously at *QualityNet.org*) has transitioned to a new uniform resource locator (URL) at *QualityNet.cms.gov*.

period during which performance or ability to submit data was impacted. However, we also believe that the hospital should still be evaluated for the remainder of the applicable period during which performance and/or ability to timely submit data was not impacted (to the extent that enough data are available to ensure that the calculation is statistically sound). This policy is not intended to extend to payment reductions. Therefore, we would like to clarify that an approved ECE for the HAC Reduction Program does not exempt hospitals from payment reductions under the HAC Reduction Program.

c. Clarification of the Impact of ECE Excluded Data for the HAC Reduction Program

In this final rule, we would also like to clarify the impact on upcoming HAC Reduction Program calculations of data excluded from the HAC Reduction Program due to the nationwide ECE. In order to determine and evaluate what kind of impact the PHE for COVID–19 might have on the HAC Reduction Program, we conducted analyses to simulate the impact of an altered performance period on program eligibility and the resulting payment impacts to hospitals using data for the FY 2020 HAC Reduction Program performance period. This analysis was intended to evaluate what patterns we might observe in HAC Reduction Program eligibility and payment as a result of excluding 6 months of data due to the ECE granted in response to the PHE for COVID–19. Our analysis for the proposed rule found that when 6 months of data are removed from HAC Reduction Program calculations, 12.2 percent of hospitals see a change in worst-performing quartile status, with 6.1 percent moving into the worst-performing quartile and 6.1 percent moving out. For context, in a typical year approximately 18 percent of hospitals experience a change in worst-performing quartile status from one year to the next. An analysis of FY 2022 data resulted in a change in worst-performing quartile status for 17.2 percent of hospitals relative to their FY 2021 worst-performing quartile status. We refer readers to Appendix A for additional information regarding the estimated numbers of hospitals in the worst-performing quartile by hospital characteristic for FY 2022.

As we stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101) and reiterated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41475), we will use a subregulatory process to make nonsubstantive updates to measure specifications to facilitate the program's operation when minor changes are required, but do not substantively impact the program's previously finalized policies (84 FR 42385 through 42387). We believe that updates to measure inclusion criteria proposed by the measure developers in response to the COVID–19 PHE are substantive and we have discussed and finalized them in this rulemaking. For more details, we refer readers to the Hospital Specific Report (HSR) User Guide located on QualityNet website at: *https://qualitynet.cms.gov/inpatient/hac/reports*.

8. Regulatory Updates (42 CFR 412.172)

We proposed to update the references to CMS resources in regulation text. We note that we renamed our *Hospital Compare* website. It is now referred to as *Care Compare* and is available at: *https://www.medicare.gov/care-compare*. We proposed to revise our regulations for the HAC Reduction Program at 42 CFR 412.172(f)(4) to reflect the new website name. We also proposed to amend § 412.172(f)(4), by adding the phrase ''or successor website'' so that the text reads ''Hospital Compare website or successor website.'' [799] We invited public comment on our proposal. We received no comments on this proposal. We are finalizing our proposal, without modification.

J. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident limit for direct GME and IME

[799] While the statute refers to *Hospital Compare,* the name has been changed to *Care Compare.* Now called *Care Compare,* the website continues to serve the purpose of displaying quality data submitted for the HAC Reduction Program.

payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances.

Section 5503(a)(4) of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than their caps, and to authorize the redistribution of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section 5503(b) amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions in the same manner to the IME FTE resident caps. The policy implementing section 5503 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPPS/ASC final rule with comment period (75 FR 72147 through 72212) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53424 through 53434). Section 5506(a) of the Affordable Care Act amended section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The policy implementing section 5506 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPPS/ASC final rule with comment period (75 FR 72212 through 72238), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53448), and the FY 2015 IPPS/LTCH final rule (79 FR 50122–50140).

2. Provisions of the Consolidated Appropriations Act, 2021

The Consolidated Appropriations Act, 2021 (CAA), division CC, contained 3 provisions affecting Medicare direct GME and IME payments to teaching hospitals. Section 126 of the CAA makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year), to be distributed beginning in fiscal year 2023, with priority given to hospitals in 4 statutorily-specified categories. Section 127 of the CAA makes statutory changes relating to the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track (RTT), and the 3-year rolling average set out at section 1886(h)(4)(G)(i) of the Act used to calculate payments for these hospitals. Section 131 of the CAA makes statutory changes to the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration. We provided detailed proposals for implementing these three CAA provisions in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25502 through 25523).

We continue to review the large number of comments on the proposed provisions relating to sections 126, 127 and 131 of division CC the Consolidated Appropriations Act, 2021 (CAA, 2021). Due to the number and nature of the comments that we received on our proposed policies, we intend to address the public comments in a separate document. We refer individuals interested in reviewing the background information and the discussion regarding these policies to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25503 through 25523).

3. Proposal for Intern and Resident Information System (IRIS) Data

Section 42 CFR 413.24(f)(5)(i) provides that a Medicare cost report for a teaching hospital is rejected for lack of supporting documentation if the cost report does not include a copy of the Intern and Resident Information System (IRIS) diskette. In accordance with 42 CFR 413.78(b) for direct GME and 42 CFR 412.105(f)(1)(iii)(A) for IME, no individual may be counted as more than one full-time equivalent (FTE). A hospital cannot claim the time spent by residents training at another hospital; if a resident spends time in more than one hospital or in a non-provider setting, the resident counts as a partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident count as a partial FTE based on the proportion of total time worked compared to the total time necessary to fill a full-time internship or residency slot.

In 1990, we established the IRIS, under the authority of sections 1886(d)(5)(B) and 1886(h) of the Act, in order to facilitate proper counting of FTE residents who rotate to more than one site (that is, hospitals, non-provider settings). Teaching hospitals use the IRIS to collect and report information on residents training in approved residency programs. Section 42 CFR 413.24(f)(5)(i) requires teaching hospitals to submit the IRIS data along with their Medicare cost reports in order to have an acceptable cost report submission. As stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25523), we are in the process of issuing a new Extensible Markup Language (XML)-based IRIS file format that captures FTE resident count data consistent with the manner in which FTEs are reported on the Medicare cost report.

After receiving the IRIS data along with each teaching hospital's cost report, the contractors upload the data to a national database housed at CMS, which can be used to identify ''duplicates,'' that is, the same time period (for example, April 1 through April 3 of a given fiscal year) being claimed by more than one hospital in their GME/IME FTE resident count. If duplicates are identified, the contractors will make the hospitals that claimed the same time aware of this situation and will correct the duplicate reporting on the respective hospitals' cost reports for direct GME and IME payment purposes.

Historically, we would collect the IRIS data from hospitals on a diskette, as referenced in 42 CFR 413.24(f)(5)(i). Because diskettes are no longer used by providers to furnish these data to contractors, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25523 through 25524), we proposed to remove the reference in the regulations to a diskette and instead reference ''Intern and Resident Information System data.'' Specifically, we proposed to amend 42 CFR 413.24(f)(5)(i) by adding a new paragraph (A) to include this proposed revised language.

In addition, to enhance the contractors' ability to review duplicates and to ensure residents are not being double-counted, we stated in the proposed rule that we believe it is necessary and appropriate to require that the total weighted and unweighted FTE counts on the IRIS for direct GME and IME respectively, for all applicable allopathic, osteopathic, dental, and podiatric residents that a hospital may train, must equal the same total weighted and unweighted FTE counts for direct GME and IME reported on Worksheet E–4 and Worksheet E, Part A of the filed Medicare cost report. The need to verify and maintain the integrity of the IRIS data has been the subject of reviews by the Office of the Inspector General (OIG) over the years. An August 2014 OIG report cited the need for CMS to develop procedures to ensure that no resident is counted as more than one FTE in the calculation of Medicare GME payments (OIG Report No. A–02–13–01014, August 2014). More recently, a July 2017 OIG report recommended that procedures be developed to ensure that no resident is counted as more than one FTE in the calculation of Medicare GME payments (OIG Report No. A–02–15–01027, July 2017).

Therefore, effective for cost reporting periods beginning on or after October 1, 2021, in the FY 2022 IPPS/LTCH PPS

proposed rule (86 FR 25524), we proposed to add the requirement that IRIS data contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME and IME FTE residents reported in the cost report. Specifically, we proposed to amend 42 CFR 413.24(f)(5)(i)(A) to state that, effective for cost reporting periods on or after October 1, 2021, the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation.

Providers would be required to use the new XML IRIS format for all cost reports with cost reporting periods beginning on or after October 1, 2021. CMS does not have a free download of the new IRIS XML format; the providers should use their vendors' software to file their IRIS report with the Medicare Administrative Contractor.

Comment: A commenter appreciated that the agency has worked with independent vendors to develop a new version of the IRIS software. However, the commenter stated that CMS expects teaching hospitals participating in the Medicare program to contract with private companies to comply with a Medicare requirement. According to the commenter, CMS should develop its own version of IRIS, make it freely available for download to Medicare-participating hospitals that train residents, and keep it updated. However, the commenter appreciated that many of the changes that they and their members suggested have been incorporated into the new versions of the software that the private vendors have developed. The commenter explained that they submitted comments on the IRIS update process to CMS in June 2018 and July 2019. According to the commenter, the general changes that have been under discussion are necessary and appropriate, and they look forward to seeing those changes finalized. However, the commenter understands that certain vendors have not made the changes yet and/or have not released new versions of their software. Thus, the commenter and other members of the public are being asked to comment on a software change that the teaching hospital members have not seen, and more importantly, have not been able to work with for any period of time. According to the commenter, teaching hospitals should be able to work with the new software format for a full cost reporting year and work through any system concerns and issues before being subject to a regulatory requirement that might result in the rejection of a hospital's Medicare cost report. Therefore, the commenter requested that CMS withdraw its proposed regulatory change until such time as the teaching hospital community has a full cost reporting year to work with the new software and work out any system problems encountered. The commenter also requested that CMS explain in more detail the process by and timeframe in which the contractor will make hospitals that claimed the same time aware of duplicates, and the expectations regarding the affected hospitals' resolutions of those duplicates.

Response: CMS is validating vendor IRIS software to ensure that it meets the IRIS XML specifications. CMS is planning on releasing the list of all approved IRIS software vendors. We understand the commenter's concern about rejection of the cost report if the submitted IRIS GME and IME FTEs do match the related counts reported in the cost reports beginning on or after October 1, 2021. However, we maintain that in order to properly identify the IRIS duplicates, it is necessary that the IME and GME FTE counts in the submitted IRIS match the related FTEs reported on the cost report. Therefore, we are finalizing revisions responsive to this concern, which are discussed below. We are not planning on issuing free IRIS software. CMS will issue a list of all approved IRIS software vendors.

The timeline for review and resolution of duplicates would be based the Medicare Administrative Contractors (MACs) schedule for reviewing of the affected cost reports. Also, the MACs would follow their established process for resolving the duplicate. Comment asking CMS to describe a detailed process for how the MACs will resolve the duplicates for hospitals that claimed the same time considered outside the scope of this rule.

Comment: A few commenters suggested that CMS should ensure that the proposal for reporting GME FTEs on the Medicare cost report is consistent with children's hospitals Medicare cost reporting 's hospitals are not reimbursed under the IPPS, they do not receive IME payments and therefore do not complete Worksheet E, Part A of the Medicare cost report. Thus, these commenters have noted that they either cannot access the worksheet or their cost reports may be flagged for errors if they attempt to submit information in the worksheet. According to the commenters, if CMS were to finalize the proposed rule, CMS must either exempt children's hospitals from this requirement, or alternatively, CMS must provide guidance and ensure that the information technology systems are updated such that children's hospitals can complete the required sections.

Response: The proposed rule that GME and IME FTEs (weighted and unweighted) reported on the IRIS data match the total FTEs reported on the Medicare cost report does not change the Medicare cost report rules. Children's hospitals and other provider types that are not reimbursed for IME are not required to report IME FTEs reported in FTEs on the Medicare cost reports. Therefore, there is no requirement that the total IME IRIS match the total IME FTEs reported in the cost report for providers that are not reimbursed for IME.

Comment: Several commenters had various concerns with the rule's proposal to require the data reported in IRIS must match data information provided in the cost report, to which it relates. A commenter explained that while they are supportive of using new technology to collect the IRIS data, they oppose the CMS' proposal to reject a cost report that lacks supporting documentation unless the IRIS data contains the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME and IME FTEs on the cost report. The commenter stated that they are concerned that hospitals may experience software issues with the new IRIS data collection system since it has not been used before. As a result, this commenter requested that the CMS consider these transition issues and not penalize hospitals for inadvertent errors that commonly arise due to the complications of recording resident rotations and that ultimately are corrected to ensure accurate Medicare payment.

A commenter added that they believe IRIS will continue to catch inadvertent errors and those errors will continue to be fixed. Therefore, the commenter believes that there is no need to impose this requirement and hospitals should not be penalized for inadvertent errors that commonly arise due to the complications of recording resident rotations and that ultimately are corrected to ensure proper Medicare payment. According to the commenter, CMS acknowledges the way in which IRIS is used when it states, in part, that if duplicates are identified, the contractors will make the hospitals that claimed the same time aware of this

situation and will correct the duplicate reporting on the respective hospitals' cost reports for direct GME and IME payment purposes. The commenter also questioned whether CMS recognized the adoption of new software program may present a technical issue for hospitals that must transition to an application they have not used before. The commenter explained that as they have learned from experience, it is not unusual for new software to have issues that may cause unintended problems.

Some of these other commenters also recommended that CMS delay this proposal to allow hospitals and MACs sufficient time to gain familiarity with this new software and address other potential process issues that could result in cost reports being inappropriately rejected.

Response: As explained in the preamble, CMS is required to review the GME & IME FTEs to identify duplicates. In order to ensure that the IRIS is identifying appropriate duplicates that the provider is actually claiming, or not claiming, in the cost report, the IRIS total GME and IME FTE counts must match the total GME and IME FTE counts claimed in the cost report. For example, if the GME FTE count (weighted or unweighted) reported in the cost report is lower than the related GME count computed from the IRIS, any duplicate identified by the IRIS may not be valid because it is possible that the cost report count does not contain the rotation or rotations that resulted in the IRIS duplicate. On the other hand, if the GME FTE count (weighted or unweighted) reported in the cost report is higher than the related GME FTE count computed from the IRIS, it is possible that the IRIS is not identifying some duplicates which are reported on the cost report. Since we are aware that there might be some rounding errors between total FTEs reported on the cost report and the IRIS data, CMS will establish a tolerance threshold for variances between total GME and IME FTE reported on the cost report and the IRIS data to account for possible rounding variances.

CMS is validating vendor IRIS software to ensure that it meets the IRIS XML specifications and will release the list of all approved IRIS software vendors. However, we agree with the commenters that we should delay the implementation of the new policy requiring MACs to reject cost reports where the total number of reported submitted IRIS GME and IME FTEs do not match the total IME and GME FTEs reported on the cost report.

After consideration of the public comments we received, we are modifying 42 CFR 413.24(f)(5)(i)(A) to require that for cost reporting periods beginning on or after October 1, 2021, the GME weighted and unweighted) and IME FTE counts on the submitted IRIS must match the total GME and IME FTE counts reported on the cost report. However, for cost reporting periods beginning on or after October 1, 2021 and before October 1, 2022, the cost reports will not be rejected if the total IME and GME FTEs (weighted and unweighted) on the submitted IRIS do not match the total related FTEs reported on the cost report.

We are also revising this sub-section to include a requirement that for cost reporting periods beginning on or after October 1, 2021, the IRIS data must be in the XML format.

L. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The demonstration has been extended three times since the original 5-year period mandated by the MMA, each time for an additional 5 years: These extensions were authorized by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) (ACA), section 15003 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act), enacted in 2016, and most recently, by section 128 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) (CAA 2021). In this final rule, we are summarizing the status of the demonstration program, as well as the methodologies for continued implementation and budget neutrality under the extension authorized by section 128 of the Public Law 116–260.

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-Hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

3. Policies for Implementing the 5-Year Extension Period Authorized by Public Law 116–260

Our policy for implementing the 5-year extension period authorized this year by Public Law 116–260 follows upon that for the previous extensions, under the ACA (Pub. L. 111–148) and the Cures Act (Pub. L. 114–255).

Section 410A of Public Law 108–173 (MMA) initially required a 5-year period of performance. Subsequently, sections 3123 and 10313 of Public Law 111–148 (ACA) required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Public Law 111–148 required the Secretary to provide for the continued participation of rural community hospitals in the demonstration program during this 5-year extension period, in the case of a rural community hospital participating in the demonstration program as of the last day of the initial 5-year period, unless the hospital made an election to discontinue participation. In addition, Public Law 111–148 limited the number of hospitals participating to no more than 30.

Section 15003 of the Cures Act required the Secretary to conduct the demonstration for a 10-year extension period (in place of the 5-year extension period required by Pub. L. 111–148 (ACA)). Specifically, section 15003 of Public Law 114–255 (Cures Act) amended section 410A(g)(4) of Public Law 108–173 (MMA) to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary would provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital made an election, in such form and manner as the Secretary may specify, to discontinue participation. In addition, section 15003 of Public Law 114–255 added subsection (g)(5) to section 410A of Public Law 108–173 to require that, during the second 5 years of the 10-year extension period, the Secretary would apply the provisions of section 410A(g)(4) of Public Law 108–

173 to rural community hospitals not described in subsection (g)(4) but that were participating in the demonstration as of December 30, 2014, in a similar manner as such provisions apply to hospitals described in subsection (g)(4).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38280), we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those previously participating hospitals choosing to participate in the second 5-year extension period. According to our finalized policy, each previously participating hospital began the second 5 years of the 10-year extension period and payment for services provided under the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255) on the date immediately after the period of performance ended under the first 5-year extension period.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by Public Law 111–148 (ACA) elected to continue in the 5-year extension period authorized by Public Law 114–255 (Cures Act). Therefore, for these hospitals, this third 5-year period of participation started on dates ranging from May 1, 2015 through January 1, 2017, depending on when they had initially started. On November 20, 2017, we announced that 13 additional hospitals had been selected to participate in the demonstration in addition to these 17 hospitals continuing participation from the first 5-year extension period. (These two groups are referred to as ''newly participating'' and ''previously participating'' hospitals, respectively.) We announced that each of these newly participating hospitals would begin its 5-year period of participation effective with the start of the first cost-reporting period on or after October 1, 2017. One of the newly participating hospitals withdrew from the demonstration program prior to beginning participation in the demonstration on July 1, 2018. In addition, one of the previously participating hospitals closed effective January 2019, and another withdrew effective October 1, 2019. Therefore, 27 hospitals were participating in the demonstration as of this date—15 previously participating and 12 newly participating.

Each hospital has had its own end date applicable to this third five-year period for the demonstration. For four of the previously participating hospitals, this end date fell within FY2020, while for 11 of the previously participating hospitals, the end date would fall within CY 2021. (One of the hospitals within this group chose in February of 2020 to withdraw effective September of the previous year). The newly participating hospitals were all scheduled to end their participation either at the end of FY 2022 or during FY 2023.

Division CC, section 128 of CAA 2021 requires a 15-year extension period (that is, an additional five years beyond the current extension period), to begin on the date immediately following the last day of the initial 5-year period, instead of the 10-year extension period mandated by the Cures Act. In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019. We, therefore, interpret the statute as providing for an additional 5-year period under the reasonable cost-based reimbursement methodology for the demonstration for the hospitals that were participating as of this date.

Given that four hospitals ended the 5-year period authorized by the Cures Act during FY 2020, we proposed to keep to the policy finalized for the previous extensions, and apply the cost-based reimbursement methodology to the date following the last day of this previous period for each hospital that elects to continue participation. Likewise, each of the 22 hospitals with a scheduled end date during 2021, 2022, or 2023 and the hospital that withdrew in February 2020 would be eligible for an additional 5-year period starting from the day after the specified end date. Accordingly, the period of participation for the last hospital in the model under this most recent legislative authorization would extend until June 30, 2028.

4. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount that the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. We note that the payment methodology for this demonstration, that is, cost-based payments to participating small rural hospitals, makes it unlikely that increased Medicare outlays will produce an offsetting reduction to Medicare expenditures elsewhere. Therefore, in the 12 IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (A different methodology was applied for FY 2017.) As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the statutory language of the budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

b. General Budget Neutrality Methodology

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming

fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. We note that we have calculated this difference for FYs 2005 through 2015 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

c. Budget Neutrality Methodology for the Extension Period Authorized by CAA 2021

For the newly enacted extension period, under CAA 2021, we proposed to continue upon the general budget neutrality methodology used in previous years, and specifically to follow upon the determinations for the previous extension period, under the Cures Act.

(1) Budget Neutrality Methodology for Previous Extension Period Under the Cures Act

We finalized our budget neutrality methodology for periods of participation under this previous 5-year extension period in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38285 through 38287). Similar to previous years, we stated in this rule, as well as in the FY 2019 and FY 2020 IPPS/LTCH PPS proposed and final rules (83 FR 20444 and 41503, and 84 FR19452 and 42421, respectively) that we would incorporate an estimate of the costs of the demonstration, generally determined from historical, ''as submitted'' cost reports for the participating hospitals, and appropriate update factors, into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In addition, we stated that we would continue to apply our general policy from previous years of including, as a second component to the budget neutrality offset amount, the amount by which the actual costs of the demonstration for an earlier, given year (as determined from finalized cost reports, when available) differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year.

In these proposed and final rules, we described several distinct components to the budget neutrality offset amount for the specific fiscal years of the extension period authorized by the Cures Act.

We included a component to our overall methodology similar to previous years, according to which an estimate of the costs of the demonstration for both previously and newly participating hospitals for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In the FY 2019 IPPS final rule (83 FR 41506), we included such an estimate of the costs of the demonstration for each of FYs 2018 and 2019 into the budget neutrality offset amount for FY 2019. In the FY 2020 IPPS final rule (84 FR 42421), we included an estimate of the costs of the demonstration for FY 2020 for 28 hospitals. In the FY 2021 IPPS final rule (85 FR 58873), we included an estimate of the costs of the demonstration for FY 2021 for the 22 hospitals for which the cost-based reimbursement methodology was to apply for all or part of FY 2021.

Similar to previous years, we continued to implement the policy of determining the difference between the actual costs of the demonstration as determined from finalized cost reports for a given fiscal year and the estimated costs indicated in the corresponding year's final rule, and including that difference as a positive or negative adjustment in the upcoming year's final rule. (For each previously participating hospital that decided to participate in the 5-year extension period under the Cures Act, the cost-based payment methodology under the demonstration began on the date immediately following the end date of its period of performance for the still previous extension period (under the ACA). In addition, for previously participating hospitals that converted to CAH status during the time period of the second 5-year extension period, the demonstration payment methodology was applied to the date following the end date of its period of performance for the first extension period to the date of conversion). In the FY 2020 final rule, we included the difference between the amount determined for the cost of the demonstration in each of FYs 2014 and 2015 and the estimated amount included in the budget neutrality offset in the final rule for each of these respective fiscal years. For FY 2016 and subsequent years, we have stated that will use finalized cost reports when available that detail the actual costs of the demonstration in these fiscal years and incorporate these amounts into the budget neutrality calculation.

(2) Methodology for Estimating Demonstration Costs for FY 2022

We are using a methodology similar to previous years, according to which an estimate of the costs of the demonstration for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2022. We are conducting this estimate for FY 2022 based on the 26 hospitals that will be continuing participation in the demonstration for the fiscal year. The methodology for calculating this amount for FY 2022 proceeds according to the following steps:

Step 1: For each of these 26 hospitals, we identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. For each of these hospitals, the ''as submitted'' cost report is that with cost report period end date in CY 2019. We sum these hospital-specific amounts to arrive at a total general amount representing the costs for covered inpatient hospital services, including swing beds, across the total 26 hospitals eligible to participate during FY 2022.

Then, we multiply this amount by the FYs 2020, 2021 and 2022 IPPS market basket percentage increases, which are calculated by the CMS Office of the Actuary. (We are using the final market basket percentage increase for FY 2022, which can be found at section V.A of the preamble to this final rule). The result for the 26 hospitals is the general estimated reasonable cost amount for covered inpatient hospital services for FY 2022.

Consistent with our methods in previous years for formulating this estimate, we are applying the IPPS market basket percentage increases for FYs 2020 through 2022 to the applicable estimated reasonable cost amount (previously described) in order to model the estimated FY 2022 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2022 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set

of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. We sum these hospital-specific amounts, and, in turn, multiply this sum by the FYs 2020, 2021 and 2022 IPPS applicable percentage increases. (For FY 2021, we are using the finalized applicable percentage increase, per section V.A of the preamble of this final rule).This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 26 hospitals (for covered inpatient hospital services, including swing beds), which will be the general estimated amount of the costs of the demonstration for FY 2022.

For this final rule, the resulting amount is $65,779,803, which we are incorporating into the budget neutrality offset adjustment for FY 2022. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical update factors for cost and payment. In the proposed rule, we stated that if updated data became available prior to the final rule, we would use them as appropriate to estimate the costs for the demonstration program for FY 2022 in accordance with our methodology for determining the budget neutrality estimate. Accordingly, we have used revised, finalized determinations for the market basket update and applicable percentage increase in formulating this estimate for the final rule.

(3) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

As described earlier, we have calculated the difference for FYs 2005 through 2015 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

In the FY 2021 proposed rule, we stated that if finalized cost reports for the entire set of hospitals that completed cost report periods under the demonstration payment methodology beginning in FY 2016 were available by the time of the final rule, we would include in the final budget neutrality offset amount the difference between the actual cost as determined from these cost reports and the estimated amount in the FY 2016 final rule. When the complete set of finalized cost reports were not available for the FY 2021 final rule, we stated that we would aim to include this difference within the FY 2022 proposed and final rules. At this time, for the FY 2022 final rule, all of the finalized cost reports are available for the 18 hospitals that completed cost report periods under the demonstration payment methodology beginning in FY 2016; these cost reports show the actual costs of the demonstration for this fiscal year to be $29,842,614. Comparing this amount to the estimated amount in the FY 2016 IPPS/LTCH final rule ($26,044,620) (80 FR 49590) shows that the actual cost exceeded the estimated cost by $3,797,994. In keeping with past practice, we are adding this amount to the estimate of the demonstration costs for FY 2022 in formulating the total budget neutrality offset amount for this upcoming fiscal year.

(4) Total Proposed Budget Neutrality Offset Amount for FY 2022

Therefore, for this FY 2022 IPPS/LTCH PPS final rule, the budget neutrality offset amount for FY 2022 is based on the sum of two amounts:

(a) the amount determined under section X.4.c (2) of the preamble of this final rule, representing the difference applicable to FY 2022 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 26 hospitals participating in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $65,779,803.

(b) the amount determined under section X.4.c(3) of the preamble of this final rule, indicating the amount by which the actual costs of the demonstration in FY 2016 as shown by finalized cost reports from that fiscal year exceed the estimated amount identified in the FY 2016 final rule. The amount of this difference is $3,797,994.

We will subtract the sum of these two amounts, or $69,577,797 from the national IPPS rates for FY 2022.

We received three public comments, all of them supportive of continuing the Rural Community Hospital Demonstration. Each of the commenters in addition, suggests specific innovations to either the demonstration or rural health financing:

Comment: A commenter requested that we use the demonstration to waive barriers under Title XVIII that prevent nurse practitioners from practicing to their full education and training.

Response: The authorizing legislation only allows waiving Title XVIII provisions that are necessary for the purpose of carrying out the demonstration program. Since the demonstration program focuses on payment enhancements for a limited number of rural hospitals, such broad waivers would not be allowed.

Comment: A commenter recommended that we use the first year of the extension period for each participating hospital as a new base year for cost-based reimbursement for the demonstration.

Response: We appreciate the comment on this specific element of the payment methodology authorized by section 410A of Public Law 108–173. The requirement under the authorizing statute is for participating hospitals to be paid for hospital inpatient services during the first year of the authorized 5-year period according to the reasonable costs of providing those services. For each of the remaining four years, payment is determined according to a methodology that imposes the reasonable cost amount from the first year as a limiting factor. The statutory language governing the respective extensions of the Rural Community Hospital demonstration requires a new base year for the 5-year extension period mandated by CCA 2021, and we will determine the hospital inpatient payment for participating hospitals accordingly.

Comment: The parent company for two of the participating hospitals notes that the demonstration does not offer long-term financial sustainability needed to maintain health care access in rural areas. The commenter recommends that we continue to examine and develop an alternative separate and distinct payment structure for the portion of cost-based reimbursement that pays for costs associated with access in rural areas.

Response: We appreciate the comment, and continue to explore alternatives for promoting access to care

in rural areas. We would like to highlight two current initiatives:

The Community Health Access and Rural Transformation (CHART) Model offers an alternative payment model opportunity for rural communities, aiming to provide financial stability to rural providers and facilitate access to high-quality care for rural beneficiaries. CMS will announce award recipients in the CHART Community Transformation Track in fall 2021.

In addition, section 125 of CAA 2021 establishes a new provider type, Rural Emergency Hospitals, which will be required to furnish emergency department services and observation care, and may provide other outpatient medical and health services as specified by the Secretary through rulemaking. We have included a Request for Information (RFI) in the Calendar Year 2022 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule to obtain feedback that will inform policy development for this new provider type.

L. Market-Based MS–DRG Relative Weight Policy—Repeal (§ 413.20)

1. Overview

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a requirement for a hospital to report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021 (85 FR 58873 through 58892); this data collection requirement is specified in 42 CFR 413.20(d)(3). We also finalized the use of this data in a new market-based methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing, beginning in FY 2024. Specifically, we finalized that we will begin using the reported median payer-specific negotiated charge by MS–DRG for MA organizations in the market-based MS–DRG relative weight methodology beginning with the relative weights calculated for FY 2024.

2. Repeal of the Market-Based MS–DRG Relative Weight Data Collection and Market-Based Methodology for Calculating MS–DRG Relative Weights

After further consideration of the many contract arrangements hospitals use to negotiate rates with MA organization payers, and the usefulness, for ratesetting purposes, of the market-based data as reported in accordance with the FY 2021 IPPS/LTCH PPS final rule, we proposed to repeal the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021. We also proposed to repeal the market-based MS–DRG relative weight methodology that was adopted effective for FY 2024, and to continue using the existing cost-based methodology for calculating the MS–DRG relative weights for FY 2024 and subsequent fiscal years. We stated in the proposed rule that comments received on the 60-day Paperwork Reduction Act (PRA) revision request of the existing information collection requirement (ICR) for cost reports, (OMB control number 0938–0050, which was published on November 10, 2020 (85 FR 71653 and 71654)), also provided further questions for us to examine regarding the usefulness of this data, and requested that we consider a delay or repeal of this policy. In light of these questions and for the reasons discussed, we proposed to repeal the market-based data collection requirement and MS–DRG relative weight methodology to allow for further consideration of these questions and possible alternative approaches.

We also proposed to amend 42 CFR 413.20(d)(3) to reflect the proposed repeal of the market-based MS–DRG relative weight data collection requirement. Specifically, we proposed to amend 42 CFR 413.20(d)(3) to remove the requirement at 42 CFR 413.20(d)(3)(i)(B) that a provider furnish the contractor its median payer-specific negotiated charge by MS–DRG for payers that are MA organizations, as applicable, and changes thereto as they are put into effect, and to renumber the existing provisions accordingly.

We stated in the proposed rule that in light of the proposal to repeal the requirement for hospitals to report this median payer-specific negotiated charge data on the cost report, we would revise the next proposed revision of the existing ICR for cost reports (OMB control number 0938–0050, expiration date March 31, 2022), accordingly.

We invited public comment on our proposal to repeal the market-based data collection requirement and market-based MS–DRG relative weight methodology. We also invited public comment on alternative approaches or data sources that could be used in Medicare fee-for-service (FFS) ratesetting. In the proposed rule, we also discussed and invited public comments on an alternative to maintain the market-based data collection requirement but delay the implementation of the market-based MS–DRG relative weight methodology to a date after FY 2024. We refer readers to 86 FR 25784 of the proposed rule for further discussion of this alternative.

Comment: Many commenters, including MedPAC, supported the proposal to repeal the market-based MS–DRG relative weight data collection requirement and market-based MS–DRG relative weight methodology (referred herein as the market-based policy). These commenters also opposed the alternative to instead maintain the requirement that hospitals report the median payer-specific negotiated charge for MA organizations on the Medicare cost report, but delay implementing the use of this data in the market-based MS–DRG relative weight methodology beyond FY 2024. These commenters expressed several of the same questions and concerns we received on the 60-day Paperwork Reduction Act (PRA) revision request of the information collection requirement (ICR), (OMB control number 0938–0050, which was published on November 10, 2020 (85 FR 71653 and 71654)). These concerns were regarding the accuracy of this data to represent hospital relative resource use, the impact reporting this data would have on market competition, the ability for the data to represent market-based prices given the relationship between MA organization and Medicare FFS rates, and the usefulness of the data generally.

Several commenters supported the proposal to repeal the market-based policy because they believed the policy to be unduly burdensome on hospitals, and argued that the current cost-based methodology for calculating the MS–DRG relative weights was functioning as intended.

MedPAC supported the proposal and noted that MA plans almost always explicitly use Medicare FFS relative weights to set their payment rates, and that using MA plans' rates to set MS–DRG relative weights would be circular and would not bring true market-based payment rates into the Medicare hospital ratesetting process. Several other commenters supported the proposal to repeal the market-based policy because they believed the policy did not inform Medicare beneficiaries with cost and quality information that would promote choice or encourage cost-conscious decisions to lower overall health care costs. These commenters argued that the market-based policy would result in shifting payments from one service to another, rather than promoting price transparency and controlling overall costs. A commenter suggested that MA organizations, instead of hospitals, were

better suited to report the median payer-specific negotiated charge that hospitals have negotiated with all of their MA organization payers, by MS–DRG.

Many other commenters urged CMS not to finalize the proposed repeal of the market-based policy. Several of these commenters stated that the market-based policy would help lower costs, improve competition and empower patients. These commenters also argued that by repealing the market-based policy, CMS would continue its reliance on the hospital chargemaster, which they believed rarely reflects true market costs. These commenters argued that the additional burden required to report this market-based data on the Medicare cost report was minimal and that repealing the policy was premature.

Other commenters argued that by repealing this market-based policy, CMS would remove a significant enforcement mechanism to promote price transparency. These commenters expressed that by repealing this policy, CMS would convey its lack of commitment to price transparency. Another commenter argued that there was no basis for proposing to repeal this policy since the court system rejected many of the hospitals' primary objections to price transparency.

Response: We appreciate the commenters' feedback on our proposed repeal of the market-based policy. We agree with commenters that we need to further consider the questions raised regarding the ability for this data to represent market-based pricing given the relationship between Medicare FFS and MA organization rates, and therefore the usefulness and appropriateness of this data for Medicare FFS ratesetting purposes.

With respect to commenters who opposed repealing the market-based policy based on the belief that the policy would lower costs, we note that the market-based MS–DRG relative weight methodology, as finalized in the FY 2021 IPPS/LTCH PPS final rule, would be normalized by an adjustment factor so that the average case weight after recalibration would be equal to the average case weight before recalibration, as is the case under the current cost-based MS–DRG relative weight methodology. As stated in the FY 2021 IPPS/LTCH PPS final rule, the normalization adjustment is intended to help ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act (85 FR 58880). Further, as stated in the FY 2021 IPPS/LTCH PPS final rule, the purpose of the market-based data collection requirement was to collect market-based data so that the data may be used within Medicare payment calculations (85 FR 58883); the focus of this policy was not on lowering costs.

With regard to commenters who opposed repealing the market-based policy because they believed repealing it would minimize CMS' commitment to, and remove a significant enforcement mechanism for, price transparency, we emphasize that we agree with commenters on the importance of price transparency for health care consumers. A repeal of the market-based policy would not affect the separate price transparency requirements CMS finalized under the Hospital Price Transparency final rule or the Transparency in Coverage final rule, nor do we believe it would signal a change in our commitment to price transparency. As stated in the FY 2021 IPPS/LTCH PPS final rule, however, the purpose of the market-based data collection requirement was not to promote transparency in health care prices but to collect market-based data for use in Medicare payment calculations (85 FR 58883).

The market-based MS–DRG relative weight data collection policy, as finalized in the FY 2021 IPPS final rule, is distinct from the requirements and penalties set forth under the Hospital Price Transparency Final Rule (84 FR 65524). As discussed more fully in the FY 2021 IPPS/LTCH PPS final rule, the market-based data collection requirement and MS–DRG relative weight methodology were finalized under the authority provided under sections 1815(a), 1833(e), 1886(d)(4)(A), 1886(d)(4)(B), and 1886(d)(4)(C) of the Social Security Act. By contrast, the Hospital Transparency Final Rule relied on separate authority under section 2718(e) of the Public Health Service Act. Similarly, the market-based policy is distinct from other CMS price transparency efforts, such as the Transparency in Coverage final rule, which relied on other authority under section 2715A of the Public Health Service Act, as well as section 1311(e)(3) of the Patient Protection and Affordable Care Act.[800]

In regards to commenters' concern that CMS is not committed to initiatives that promote competition, on July 9, 2021, President Biden issued an Executive Order (E.O.) on *Promoting Competition in the American Economy.* This E.O. directed the Department of Health and Human Services to support existing price transparency initiatives for hospitals, other providers and issuers, along with any new price transparency initiatives or changes made necessary by the No Surprises Act (Pub. L. 116–260, 134 Stat. 2758) or any other statutes. As stated previously, the purpose of the market-based policy was to collect market-based data so that the data may be used within Medicare payment calculations and is separate from CMS price transparency initiatives. This E.O. further reiterates CMS' commitment to current and future price transparency initiatives.

As noted, CMS previously finalized the Hospital Price Transparency final rule which, as of January 1, 2021, requires each hospital operating in the United States to provide clear, accessible pricing information about the items and services they provide in two ways: (1) Comprehensive machine-readable file with all items and services, and (2) display of shoppable services in a consumer-friendly format. Hospital price transparency helps Americans know what a hospital charges for the items and services it provides. We expect hospitals to comply with these legal requirements, and are enforcing these rules to ensure Americans know what a hospital charges for items and services. CMS began auditing hospital websites for compliance with the requirements of the Hospital Price Transparency final rule in January 2021, and began issuing warning letters to hospitals in April 2021. We will continue our monitoring and enforcement activities to ensure compliance with the Hospital Price Transparency requirements.

With regard to the commenters who opposed repealing the market-based policy because they believed it would remove a significant enforcement mechanism for price transparency, we note that in the recently published CY 2022 OPPS/ASC proposed rule we proposed to improve our enforcement and compliance efforts by increasing the penalty for hospitals that do not comply with Hospital Price Transparency final rule. Specifically, CMS proposed to set a minimum civil monetary penalty of $300/day that would apply to smaller hospitals with a bed count of 30 or fewer, and apply a penalty of $10/bed/day for hospitals with a bed count greater than 30, not to exceed a maximum daily dollar amount of $5,500. CMS takes seriously the concerns it has heard from consumers that hospitals are not making clear, accessible pricing information available online, as they have been required to do since January 1, 2021. The public is encouraged to submit complaints of noncompliance through our website: *https://www.cms.gov/hospital-price-transparency/contact-us.*

[800] Public Law 111–148.

Additionally, on December 27, 2020, the Consolidated Appropriations Act, 2021 was enacted.[801] Title I (No Surprises Act) and Title II (Transparency) of Division BB of the CAA established new protections for consumers related to surprise billing and transparency in health care. On July 1, 2021, the Department of Treasury, the Department of Labor, the Office of Personnel Management, and the Department of Health and Human Services, released an interim final rule with comment (IFC) entitled, ''Requirements Related to Surprise Billing; Part I.'' [802] This IFC implements provisions of Title I (No Surprises Act) of Division BB of the CAA and establishes new protections from surprise billing and excessive cost-sharing for consumers receiving health care items and services. CMS remains committed to implementing these statutory requirements to promote transparency in health care.

As a result of these price transparency initiatives, we believe consumers will have readily available access to health care pricing information that may empower patients and may help lower costs. For the reasons discussed, as evidenced by these rules, we disagree with commenters who stated that repealing this market-based policy would convey a lack of commitment by CMS to enforcing the price transparency requirements, enhancing competition, and promoting price transparency generally.

After consideration of the comments received, and for the reasons discussed, we are finalizing our proposal to repeal this market-based data collection requirement and market-based MS–DRG relative weight methodology that was adopted effective for FY 2024, and to continue using the existing cost-based methodology for calculating the MS–DRG relative weights for FY 2024 and subsequent fiscal years. We will continue to consider these comments and questions in connection with any potential future proposed changes to the MS–DRG relative weight ratesetting process, as applicable.

Comment: Several commenters commented on our request for alternative approaches or data sources that could be used in Medicare FFS ratesetting. These commenters encouraged CMS to consider alternative data sources that incentivize value-based care, reduce costs, improve care quality, account for various risk-based contracting arrangements, and counter the practice of charge compression, without creating undue burden on hospitals, especially rural hospitals. Other commenters requested that if CMS reduced its reliance on the hospital chargemaster, that CMS contemplate the other ways in which the chargemaster is used in other payment methodologies.

A commenter requested that CMS exercise caution in changing the current MS–DRG relative weight methodology and further requested that CMS work closely with the stakeholder community to analyze the impact before making any potential change. Other commenters requested that CMS pursue potential improvements in the ratesetting process without exposing confidential negotiations with competing payers. Several other commenters stated that hospitals continue to combat the COVID–19 pandemic, and requested that as CMS assesses alternative data sources that it recognizes that additional flexibilities may be necessary as hospitals continue to recover from the COVID–19 public health emergency (PHE).

Response: We appreciate commenters' suggestions on alternative approaches and data sources that could be used in Medicare FFS ratesetting. We will continue to evaluate and consider these recommendations, including commenters' concerns regarding the impact of the COVID–19 PHE, as we consider these alternative approaches and data sources.

Comment: Several commenters expressed opinions and concerns related to CMS price transparency efforts, including suggestions related to harmonizing the Hospital Price Transparency final rule and the No Surprises Act requirements.

Response: As stated in the Hospital Price Transparency final rule, we remain open to revisiting in future rulemaking the hospital price transparency requirements should we find it necessary to make improvements in the display and accessibility of hospital standard charge information for the public (84 FR 65559). While we did not request comments in this proposed rule on either the requirements set forth in the Hospital Price Transparency final rule or related to the No Surprises Act, in the CY 2022 OPPS/ASC proposed rule we recently proposed revisions to the Hospital Price Transparency final rule policies (*https://www.federalregister.gov/public-inspection/2021-15496/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment.*).

After consideration of the comments received, and for the reasons discussed, we are finalizing our proposal to repeal the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021, without modification. We also are finalizing our proposal to repeal the market-based MS–DRG relative weight methodology that was adopted effective for FY 2024, and to continue using the existing cost-based methodology for calculating the MS–DRG relative weights for FY 2024 and subsequent fiscal years, without modification. We are also finalizing our proposed amendment to 42 CFR 413.20(d)(3) to reflect the repeal of the market-based MS–DRG relative weight data collection requirement, without modification. We are not finalizing the alternative we considered to maintain the market-based data collection requirement but delay the implementation of the market-based MS–DRG relative weight methodology to a date after FY 2024.

As discussed, we will continue to evaluate and consider the usefulness and appropriateness of market-based data for ratesetting purposes. This includes further consideration of the comments we received regarding potential alternative approaches and data sources for use in Medicare FFS ratesetting, which we will consider as applicable. As discussed, we remain committed to promoting transparency in health care prices and promoting competition in the American economy.

M. Payment Adjustment for CAR T-Cell Clinical Trial and Expanded Access Use Immunotherapy Cases (§§ 412.85 and 412.312)

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58599 through 58600), we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. We refer the reader to section II.D.2. of this final rule for discussion of the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies that we proposed and are finalizing for assignment to MS–DRG 018 for FY 2022. In the FY 2021 IPPS/LTCH PPS final rule, we modified our relative weight methodology for MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, we finalized to not include claims determined to be clinical trial claims that group to new MS–DRG 018

[801] Public Law 116–260.

[802] 86 FR 36872 (July 13, 2021).

when calculating the average cost for new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600).

In the FY 2021 IPPS/LTCH PPS final rule, we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access immunotherapy cases that would group to MS–DRG 018 (85 FR 58842) using the same methodology that we used to adjust the case count for purposes of the relative weight calculations. Specifically, after consideration of public comments, we finalized our proposal to apply a payment adjustment to claims that group to new MS–DRG 18 and include ICD–10–CM diagnosis code Z00.6, with the modification that when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We also finalized that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case. We codified this payment adjustment at 42 CFR 412.85 (for operating IPPS payments) and 42 CFR 412.312 (for capital IPPS payments), for claims appropriately containing Z00.6, as described previously, including to reflect that the adjustment will also be applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, the adjustment is not applicable to cases where the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. We also finalized our regulations at 42 CFR 412.85(c) to reflect that the adjustment factor will reflect the average cost for cases to be assigned to MS DRG 018 that involve expanded access use of immunotherapy or are part of an applicable clinical trial to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of a clinical trial. (85 FR 58844).

Using the same methodology from the FY 2021 IPPS/LTCH PPS final rule, we proposed to apply an adjustment to the payment amount for clinical trial cases that would group to MS–DRG 018 (85 FR 58842), which is the same methodology we proposed to use to adjust the case count for purposes of the relative weight calculations:

- Calculate the average cost for cases to be assigned to MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for cases to be assigned to MS–DRG 018 that do not contain ICD–10–CM diagnosis code Z00.6 or standardized drug charges of at least $373,000.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for clinical trial cases that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

Additionally, we are continuing our finalized methodology for calculating this payment adjustment, such that: (a) When the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases. However, we continue to believe to the best of our knowledge there are no claims in the historical data (FY 2019 MedPAR) used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000.

Consistent with our calculation of the adjustor for the relative weight calculations, and our proposal to use the FY 2019 data for the FY 2022 ratesetting, we proposed to continue to calculate this adjustor based on the March 2020 update of the FY 2019 MedPAR file for purposes of establishing the FY 2022 payment amount. Specifically, we proposed to multiply the FY 2022 relative weight for MS–DRG 018 by an adjustor of 0.17 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018, which under our proposal (as finalized elsewhere in this rule) includes CAR T-cell and non-CAR T-cell therapies and other immunotherapies. We refer the reader to section II.D.2. for a further discussion of MS–DRG 018. As discussed in section I.F. of this final rule, we also solicited comments on an alternative approach of using the same FY 2020 data that we would ordinarily use for purposes of the FY 2022 rulemaking, which we stated we may consider finalizing for FY 2022 based on consideration of comments received. We noted that using the methodology as finalized in the FY 2021 IPPS/LTCH PPS final rule, we calculated an adjustor of 0.25 based on this alternative approach of using the FY 2020 MedPAR file. As discussed in section I.F. of this final rule, after consideration of comments received and for the reasons discussed, CMS is finalizing the use of the FY 2019 MedPAR data to determine the MS–DRG relative weights for FY 2022.

Comment: Some commenters requested that we use the calculated adjustment of 0.25 developed from our alternative approach of using the FY 2020 MedPAR data.

Response: As previously noted, CMS is finalizing the use of the FY 2019 MedPAR data to determine the MS–DRG relative weights for FY 2022, including the relative weight for MS–DRG 018. Accordingly, we disagree that we should use the adjustment of 0.25 calculated from the FY 2020 MedPAR data instead of the 0.17 adjustment calculated from the FY 2019 MedPAR data. Given that under the IPPS, the relative weight assigned to each MS–DRG reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other MS–DRGs, it would be inappropriate to use the FY 2019 MedPAR to approximate the relative resource use for each MS–DRG, including the majority of MS–DRG 018 cases, but then a different data source (the FY 2020 MedPAR) to determine the relative resources required for MS–DRG 018 cases that are expanded access or clinical trial cases to calculate the adjustor.

After consideration of comments received, we are finalizing our proposed adjustment of 0.17, which will be multiplied by the final FY 2022 relative weight for MS–DRG 018 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018.

VI. Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF) × (COLA for hospitals located in Alaska and Hawaii) x (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Annual Update for FY 2022

The annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2022 is discussed in section III. of the Addendum to this FY 2022 IPPS/LTCH PPS final rule.

In section II.C. of the preamble of this FY 2022 IPPS/LTCH PPS final rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we are making for FY 2022, in accordance with the amendments made to section 7(b)(1)(B) of Pubic Law 110–90 by section 414 of the MACRA. Because these provisions require us to make an adjustment only to the operating IPPS standardized amount, we are not making a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

We also note that in section V.M. of the preamble of this final rule, we discuss our finalized adjustment to the payment amount for certain clinical trial or expanded access use immunotherapy cases that will group to MS–DRG 018 for both operating IPPS payments and capital IPPS payments. We refer readers to section V.M.D of this preamble for additional details on the payment adjustment for these cases.

VII. Changes for Hospitals Excluded From the IPPS

A. Rate-of-Increase in Payments To Excluded Hospitals for FY 2022

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting

period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs. Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short–term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating basket to a 2014 base year, effective for FY 2018 and subsequent fiscal years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. As discussed in section IV. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to rebase and revise the IPPS operating basket to a 2018 base year. Therefore, we proposed to use the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years. Accordingly, for FY 2022, the rate-of-increase percentage to be applied to the target amount for these hospitals would be the FY 2022 percentage increase in the proposed 2018-based IPPS operating market basket.

For the FY 2022 IPPS/LTCH PPS proposed rule, based on IGI's 2020 fourth quarter forecast, we estimated that the proposed 2018-based IPPS operating market basket update for FY 2022 would be 2.5 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2022 rate-of-increase percentage that would be applied to the FY 2021 target amounts in order to calculate the FY 2022 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be 2.5 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we proposed that if more recent data became available for the FY 2022 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2022.

For FY 2022, we are finalizing the rebased and revised 2018-based IPPS operating market basket without modification. However, as we proposed, we are incorporating more recent data available for this final rule. Based on IHS Global Inc.'s second-quarter 2021 forecast, the IPPS operating market basket update for FY 2022 is 2.7 percent.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2022, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2022, the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for FY 2022, which would be equal to the percentage increase in the hospital market basket, which was estimated to be the percentage increase in the proposed 2018-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2022 was 2.5 percent, which is based on IGI's 2020 fourth quarter forecast. Furthermore, we proposed that if more recent data became available for the FY 2022 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2022.

For FY 2022, we are finalizing the rebased and revised 2018-based IPPS operating market basket without modification. However, as we proposed, we are incorporating more recent data available for this final rule. Based on IHS Global Inc.'s second-quarter 2021 forecast, the IPPS operating market basket update for FY 2022 is 2.7 percent.

We received no comments in response to these proposals. As such, we are finalizing as we proposed. Incorporating more recent data available for this final rule, as we proposed, we are adopting a 2.7 percent update for FY 2022.

B. Report on Adjustment (Exception) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, adjusting, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the

fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested in order to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we are publishing data on adjustment payments that were processed by the MAC or CMS during FY 2019.

The table that follows includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2020. As indicated previously, the adjustments made during FY 2020 only pertain to cost reporting periods ending in years prior to FY 2020. Total adjustment payments made to IPPS-excluded hospitals during FY 2020 are $5,088,002. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Cancer Hospitals	2	$10,677,342	$1,462,829
Children's Hospitals	6	$4,413,902	$3,018,578
RNHCIs	6	$920,503.00	$606,595
Total	**14**	**$16,011,747**	**$5,088,002**

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

a. Background and Overview

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58896), section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275), as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is a Medicare Rural Hospital Flexibility Program (MRHFP) grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. Section 123(d)(2)(B) of Public Law 110–275, as amended, limited participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public Law 110–275 required the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, we released a request for applications (RfA) for the FCHIP Demonstration. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as states meeting the statutory eligibility requirement for participation in the demonstration. The RfA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and to describe a proposal to enhance health-related services that would complement those currently provided by the CAH and better serve the community's needs. In addition, in the RfA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the MHRFP. The RfA identified four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility

beds, ambulance services, and home health services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Ten CAHs were selected for participation in the demonstration, which started on August 1, 2016, and concluded on July 31, 2019 (referred to in this section as the ''initial period''). The selected CAHs were located in Montana, Nevada, and North Dakota, and participated in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58896). Eight CAHs participated in the telehealth intervention, three CAHs participated in the skilled nursing facility/nursing facility bed intervention, and two CAHs participated in the ambulance services intervention. Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention included in the RfA.

b. Intervention Payment and Payment Waivers

CMS waived certain Medicare rules for CAHs participating in the demonstration to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: Telehealth services, ambulance services, and skilled nursing facility/nursing facility (SNF/NF) beds expansion. The payments and payment waiver provisions only applied if the CAH participated in the associated intervention. The FCHIP payment waivers consisted of the following:

(1) Telehealth Services Intervention Payments

CMS waived section 1834(m)(2)(B) of the Social Security Act (the Act), which specifies the facility fee to the originating site (that is, the participating CAH where the eligible telehealth individual is located). CMS modified the facility fee payment specified under section 1834(m)(2)(B) of the Act to allow for reasonable cost-based reimbursement to the participating CAH. CMS reimbursed the participating CAH serving as the originating site at 101 percent of its reasonable costs for overhead, salaries, fringe benefits, and the depreciation value of the telehealth equipment at the participating CAH. The Demonstration waiver did not fund or provide reimbursement for the participating CAHs to purchase new telehealth equipment. However, if a participating CAH purchases new equipment, CMS would continue to reimburse depreciation costs for that equipment. The payments to the distant site physician or practitioner were made as usual under the Medicare physician fee schedule. CMS did not waive any other provisions of section 1834(m) of the Act, including the scope of Medicare telehealth services as established under section 1834(m)(4)(F) of the Act.

(2) Ambulance Services Intervention Payments

CMS waived 42 CFR 413.70(b)(5)(C), which provides that payment for ambulance services furnished by a CAH, or an entity owned and operated by a CAH, is 101 percent of the reasonable costs of the CAH or the entity in furnishing the ambulance services if the CAH or entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. Under the demonstration, a participating CAH was paid 101 percent of reasonable costs for its ambulance services regardless of whether there was any other provider or supplier of ambulance services located within a 35-mile drive of the participating CAH or CAH-owned and operated entity. Cost-based payment was not allowed for any new capital expenditures (for example, vehicles) associated with ambulance services. This waiver did not modify any other Medicare rules affecting the provision of ambulance services.

(3) SNF/NF Beds Expansion Intervention Payments

CMS waived 42 CFR 485.620(a) and 42 CFR 485.645(a)(2), which limit CAHs to maintaining no more than 25 inpatient beds, including beds available for acute inpatient or swing bed services. Through this waiver, CAHs participating in the SNF/NF intervention were allowed to keep up to 10 additional beds (for a total of up to 35 beds) available for acute inpatient or swing bed services; however, the participating CAHs were only to use these additional beds for nursing facility or skilled nursing facility level of care. SNF/NF services furnished in the additional beds were reimbursed according to the standard Medicare reimbursement principles for CAHs. Additional capital expenditures were not allowed under this waiver. No changes to the methodology for calculating Medicare payments for swing bed services at participating CAHs were allowed. The Conditions of Participation (CoPs) for certified critical access hospitals providing (SNF/NF) long term care services are at 42 CFR 485.645. Certification to participate in Medicare's swing bed program is a separate approval by CMS from the certification to operate as a CAH provider of services. The participating CAHs within the SNF/NF Beds Expansion intervention were required to receive approval from and be certified by CMS to participate in the Demonstration swing bed program.

c. Budget Neutrality Requirement

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we finalized a policy to address the budget neutrality requirement for the demonstration. We also discussed this policy in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58996), but did not make any changes to the policy that was adopted in FY 2017. As explained in the FY 2017 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we adopted in the FY 2017 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the

event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we stated that we would comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the FCHIP Demonstration was projected to satisfy the budget neutrality requirement and likely yield a total net savings. In the FY 2017 IPPS/LTCH PPS (81 FR 57064 through 57065) final rule, we estimated that the total impact of the payment recoupment (if needed) would be no greater than 0.03 percent of CAHs' total Medicare payments (that is, Medicare Part A and Part B) within 1 fiscal year. We also explained that the final budget neutrality estimates for the FCHIP Demonstration would be based on costs incurred during the initial period of the demonstration from August 1, 2016, through July 31, 2019.

d. FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2021 IPPS/LTCH PPS final rule, our goal was to maintain the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments to the participating CAHs resulting from the demonstration). The analysis of budget neutrality identified both the costs related to providing the intervention services under the FCHIP Demonstration and any potential downstream effects of the intervention-related services, including any savings that may have accrued.

The budget neutrality analytical approach incorporated two major data components: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2021 IPPS/LTCH PPS final rule (85 48432 through 59107), we computed the cost of the demonstration for each fiscal year of the demonstration period using Medicare cost reports for the participating CAHs, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention services.

e. General Analytical Approach

The budget neutrality assessment sought to determine if the goal to maintain budget neutrality of the demonstration on its own terms was met. We examined the difference in expenditures for groups of beneficiaries who received intervention services at demonstration CAHs or at comparison CAHs that were not participating in the demonstration. The demonstration and comparison groups were composed of Medicare beneficiaries receiving an intervention service (that is, telehealth, SNF/NF or ambulance) at participating CAHs and non-participating CAHs, respectively. To ensure that there was no cross contamination between the two groups, the demonstration and comparison groups were mutually exclusive of each other, and beneficiaries who received intervention services at both participating and non-participating CAHs were included within the demonstration group only.

Medicare reimbursement for the demonstration intervention services depended on the service provided. For the swing bed services, the demonstration CAH swing bed reimbursement was based on 101 percent of the reasonable cost of the SNF services furnished in the swing beds (as computed in the Medicare cost report). The CAHs were paid on an interim basis using a per diem rate for routine and ancillary costs. For the demonstration ambulance and telehealth services, CAH reimbursement was based on 101 percent of the reasonable cost of providing the services to Medicare patients (as computed in the Medicare cost report). The CAHs were paid on an interim basis using a percentage of Medicare charges. The applicable percentage of Medicare charges was calculated by dividing the overall allowable Medicare costs by the overall Medicare charges in order to determine the Medicare cost-to-charge ratio.

The three intervention services were different, and each demonstration CAH had the option to implement one, two or all three interventions. Therefore, budget neutrality was analyzed for each demonstration intervention service separately. The basic approach to the analysis was similar for each intervention service, but some additional variables were incorporated based on the nature of the intervention and its expected impact. The findings for each intervention service were then combined at the end of the process to reach a single conclusion regarding budget neutrality for the initial period of the demonstration as a whole.

f. Data Elements

Beginning with the cost report data, CMS conducted Medicare cost report audit reviews for the 10 participating CAHs over the course of the three-year initial period. The cost reports are a collection of worksheets that calculate the costs of a specific provider for supplying health care services to Medicare beneficiaries and when aggregated these cost reports furnish information used by researchers, actuaries and policy makers. All CAHs participating in the Medicare program are required to submit cost reports annually, with the reporting period based on the provider's accounting year. It should be noted the FCHIP Cost Report audits calculated budget neutrality as determined only by the change in the cost of providing services to Medicare beneficiaries through the Medicare cost report and excluded other factors that may also influence aggregate cost to the Medicare program, such as a shifting of essential services to CAHs from more expensive tertiary hospitals or other downstream cost impacts.

The intervention services authorized under the demonstration may impact cost in several ways that can act to either increase or decrease expenditures. For example, the transition from a facility fee payment to the originating site to cost-based reimbursement under the telehealth services intervention would likely result in increased costs for those services. However, the Medicare administrative claims analysis anticipated and measured that telehealth intervention services furnished under the demonstration may also produce savings through better management of chronic conditions, reduction in air transports, and reduction in transfers to other and/or more expensive facilities. In general, the intervention services under the demonstration may affect access to services and referral patterns that, in turn, may affect utilization and therefore costs. In order to capture the full impact of the interventions, CMS developed a statistical modeling, Difference-in-Difference (DID) regression analysis to estimate

demonstration episode expenditures and compute the impact of expenditures on the intervention services by comparing cost data for the demonstration and non-demonstration groups using Medicare administrative claims across the 36-month period of performance under the initial period of demonstration. Analyses were conducted separately for each intervention service using regression-based methods that controlled for demographics, diagnostic conditions, hierarchical condition categories (HCC) risk scores, and other factors. Results were combined across the three intervention services to produce a summary conclusion regarding budget neutrality for the initial period of the demonstration as a whole.

This general analytic approach involved the comparison of total episode expenditures for beneficiaries receiving intervention services from CAHs in the demonstration group to the expected expenditures absent the demonstration. The projection of expected expenditures absent the demonstration included an additional adjustment to reflect the statistical uncertainty of the predictions. If actual expenditures for the intervention services furnished by CAHs in the demonstration group exceeded the expected expenditures absent the demonstration (with the adjustment for statistical uncertainty), then budget neutrality could potentially be violated. CMS conducted a series of analytical steps as previously described to determine the budget neutrality outcome for the initial period of the demonstration.

g. Methodology for Estimating Demonstration Costs

Step 1: The Medicare cost reports for CAHs participating in the FCHIP Demonstration were reviewed to verify reasonableness of reported expenses, revenues and statistics and to ensure the reported demonstration expenses were allowable and accurately allocated on the cost report. CMS performed a reasonableness analysis of the cost reports for each of the demonstration CAHs that focused on cost incurred by the CAH to determine whether the costs were necessary and proper for patient care under the demonstration. CMS also performed an allowability analysis for each demonstration CAH to determine which costs were directly related to the demonstration and to ensure all reported costs related to the intervention services were accounted for. In addition, each demonstration CAH's cost reports were audited to ensure the reported expenses were allowable and accurately allocated to each intervention service considering established Medicare regulations as modified by demonstration requirements. Demonstration costs that were unrelated to patient care were deemed not allowable. The cost report audit analysis included removal of any cost claimed by demonstration CAHs that was not specifically described in '(b) Intervention Payment and Payment Waivers', which describes the Medicare rules and payments methods that were actually made under the demonstration for each of the three interventions.

For each of the 10 demonstration CAHs, we identified the reasonable cost amount calculated under the reasonable cost-based methodology for the demonstration covered inpatient hospital services and covered outpatient hospital services, including swing bed, telehealth, and ambulance services as indicated on the ''as submitted'' cost report for each hospital cost reporting period covering the initial period of performance for the demonstration from August 1, 2016, through July 31, 2019. For each of the demonstration CAHs, these ''as submitted'' cost reports are those with cost report period end dates in Calendar Year (CY) 2016, 2017, 2018, 2019 and 2020. We note that among the demonstration CAHs with ''as submitted'' cost reports in CY 2020, the cost reporting period covered January 1, 2019, to December 31, 2019; March 1, 2019, to April 30, 2020; or July 1, 2019, to June 30, 2020.

Step 2: CMS utilized Hospital 2552–10 Cost Report Data files to calculate the change in Medicare reimbursement for the initial period of performance. CMS calculated Medicare reimbursement costs under the demonstration versus Medicare reimbursement costs without the demonstration. ''Medicare reimbursement costs without the demonstration'' were defined as Medicare costs as determined using the Medicare payment methodologies that would have applied absent the demonstration and represented the baseline costs for each intervention service. ''Medicare reimbursement costs under the demonstration'' were defined as the costs as determined through the audited cost report after the application of the demonstration payment waiver methodologies. The difference between these costs represented the cost impact of the demonstration.

For each of the participating CAHs, we identified the estimated amount that would otherwise be paid under applicable Medicare payment methodologies for covered intervention services (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. (Also, as indicated on the same set of ''as submitted'' cost reports as in Step 1), we identified the estimated amount that was paid for covered intervention services under the demonstration. To compute the aggregate change in cost due to the demonstration, we calculated the difference in the costs of intervention services between ''Medicare reimbursement costs without the demonstration'' versus ''Medicare reimbursement costs under the demonstration'' from the cost reports.

Step 3: For each of the 10 CAHs, Medicare administrative claims and enrollment data for beneficiaries receiving demonstration intervention services were identified. The data were collected at the individual beneficiary level and included information on service type, service date, and reasonable cost payment amount calculated under the reasonable cost-based methodology for covered intervention services furnished under the demonstration. Codes indicating diagnosis and the specific procedure provided under the demonstration were also identified using the claims and enrollment data and were used in the analysis.

Step 4: CMS defined ''episodes of care'' for the eligible CAHs. For each of the participating CAHs, using Medicare administrative claims, we identified costs related to providing demonstration intervention services. The demonstration CAHs submitted Medicare claims for the demonstration intervention services. These claims were consolidated by the Medicare Administrative Contractor (MAC) into interim payments, which were incorporated into an episode of care framework for purposes of the budget neutrality calculation. CMS defined an episode of care as all Medicare Parts A and B services furnished to a beneficiary receiving a demonstration intervention service during a specified period of time ranging from 30 to 60 days following the receipt of a demonstration intervention service. The specific timeframes for the episodes of care were chosen for each intervention based on observed expenditure patterns following an episode-triggering intervention service.

Episode costs were defined as the cost of all Medicare Parts A and B services provided to the beneficiary during the episode. Next, CMS incorporated the claims and interim payment data into the episode of care framework.

Step 5: CMS constructed Episode of Care Comparison groups and potential savings variables. We separated the episode of care Medicare Parts A and B

expenditures into two groups—expenditures for beneficiaries receiving intervention services from demonstration group CAHs and expenditures for beneficiaries receiving intervention services from non-demonstration (comparison) group CAHs within the FCHIP eligible States (Montana, Nevada, and North Dakota). Then we compared episode of care expenditures for beneficiaries receiving intervention services from demonstration group CAHs to those for beneficiaries receiving intervention services from comparison group CAHs.

Step 6: CMS conducted the Difference-in-Difference Analysis. Using the episode of care framework described in Step 4, the demonstration and comparison groups were used to measure the impact of the intervention services on episode expenditures through a DID analysis comparing baseline and performance period costs for the demonstration groups and comparison groups. The DID regression model was estimated using episode expenditures as the dependent variable. (The model's functional form was a generalized linear model with a log link and gamma distribution. This type of model is commonly used in analyzing health care expenditures and yields only positive predicted values.) All analyses were carried out separately for the three intervention services. Using the episode of care approach enabled us to identify downstream effects of the intervention services, including any savings that may have accrued. For each of the participating CAHs we identified cost-savings or reductions in transfers and admissions to other health care providers, offsetting any increase in Medicare payments that may have resulted from the use of intervention services. Results were combined across the ten CAH participants and across the three interventions to produce a summary conclusion regarding budget neutrality for the 36-month initial demonstration performance period.

Step 7: Lastly, CMS performed a supplementary sensitivity analysis adjustment for statistical uncertainty. The DID analysis results obtained using the Medicare administrative claims data were then reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. The Medicare cost reports provide another source of data related to demonstration expenditures beyond the information that is directly reported via Medicare administrative claims. The Medicare cost report audit findings were used to reconcile the directionality and outcome of the DID regression analysis results. The sensitivity analysis was calculated for the demonstration as a whole to ensure the budget neutrality conclusion via the DID analysis was not the result of random variation or statistical uncertainty of the predictions used in the analysis.

g. Budget Neutrality Conclusion

Based on analysis of the Medicare administrative claims data and the Medicare cost report audit data from the 36 months of the initial demonstration performance period, there were no statistically significant findings that the FCHIP Demonstration resulted in additional expenditures. The DID analysis results were based on an episode of care point estimate threshold. If the actual episode expenditures of the demonstration exceeded the expected expenditures absent the demonstration (with the sensitivity analysis adjustment for statistical uncertainty) then the requirement for budget neutrality under section 123(g)(1)(B) of Public Law 110–275 could potentially be violated. CMS found in aggregate that the demonstration CAHs' episode of care expenditures during the initial period of the demonstration were lower than expenditures would have been absent the demonstration. In fact, when the sensitivity analysis (using a 95 percent confidence interval) was calculated it showed that total expenditures for the 10 participating CAHs in the demonstration would need to cumulatively increase cost by more than 18 percent (which translated to $3,120 per episode, or a total of $3,529,039 for the three interventions combined) to exceed expenditures absent the demonstration. When we compared the total cost of Medicare episodes of care under the demonstration with the aggregate demonstration cost findings based on the audit of Medicare cost reports, we also found that the aggregate demonstration intervention services cost on the ''as submitted'' Medicare cost reports fell within the point estimate threshold—therefore, the FCHIP Demonstration did not result in additional expenditures during the initial period of the demonstration.

Under the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years, beginning in CY 2020. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58895), we stated that based on the currently available data, the determination of budget neutrality results was preliminary and the amount of any reduction to CAH payments that would be needed in order to recoup excess costs under the demonstration remained uncertain. Therefore, we revised the policy originally adopted in the FY 2017 IPPS/LTCH PPS final rule, to delay the implementation of any budget neutrality adjustment and stated that we would revisit this policy in rulemaking for FY 2022, when we expected to have complete data for the demonstration period. Based on the data and actuarial analysis described previously, we have concluded that the initial period of the FCHIP Demonstration (covering the performance period August 1, 2016, to July 31, 2019) has satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, we did not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2022. This policy will have no impact for any national payment system for FY 2022.

3. Provisions of the Consolidated Appropriations Act of 2021 (Pub. L. 116–159)

As stated earlier, section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act, authorized the Secretary to conduct the Frontier Community Health Integration Project (FCHIP) demonstration for a 3-year period. Section 129 of the Consolidated Appropriations Act (Pub. L. 116–159) extends the FCHIP Demonstration by 5 years. Specifically, the Consolidated Appropriations Act amended subsection (f) of section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395i–4 note) in paragraph (1), by striking ''3-year period beginning on October 1, 2009'' and inserting ''3-year period beginning on August 1, 2016 (referred to in this section as the ''initial period''), and 5-year period beginning on July 1, 2021 (referred to in this section as the ''extension period''). The Secretary is required to conduct the demonstration for an additional 5-year period. Only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. In the FY 2022 IPPS/LTCH PPS proposed rule, CMS explained the provisions of the Consolidated Appropriations Act of 2021 (Pub. L. 116–159) and states the FCHIP Demonstration will resume on July 1, 2021. The eligible CAH participants have elected to change the number of interventions and payment waivers they would participate in during the extension period. CMS consideration of these updates requires a delay in the effective date for starting the extension period that was published

in the proposed rule. We are updating our date for starting the extension period of the demonstration from July 1, 2021 to January 1, 2022. CAHs participating in the demonstration during the extension period shall begin their participation in the cost reporting year that begins on or after January 1, 2022. During the delay, CMS will complete several actions with the CAHs to develop and/or update the intervention payment waivers for the demonstration extension period. In addition, CMS will be issuing a new participation agreement outlying the demonstration terms and conditions for the participating CAHs new performance period that shall begin on or after January 1, 2022. CMS informed the CAHs participating in the extension period of the change and the CAHs have not expressed concerns about the revised effective date.

While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, based on the data available upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. We will determine the budget neutrality approach for the FCHIP Demonstration extension period once data is available for the extension period.

We received no comments on this proposal and therefore are finalizing this provision without modification.

VIII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2022

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital that has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs (''subclause II'' LTCHs). However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals,'' to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resource use and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this final rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate

(SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to 82 FR 38299.)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide-all payer systems, subject to the rate-of increase test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

4. Best Available Data

In section I.F. of the preamble of this final rule, we discussed how claims data from the MedPAR files and cost report data from HCRIS are the primary sources of data used in IPPS and LTCH PPS ratesetting. (We use the term ''ratesetting'' to describe the methods and processes we follow in determining the annual LTCH PPS payment rates and factors.) We also stated that our goal is to always use the best available data overall for ratesetting. Ordinarily, the best available claims data for the LTCH PPS ratesetting is the MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking, because in general it is the most complete full fiscal year of claims data available at the time of development of the rule. Therefore, for FY 2022 ratesetting, under ordinary circumstances, the best available claims data would be the FY 2020 MedPAR file. Similarly, the best available cost report data for LTCH PPS ratesetting is ordinarily from the HCRIS dataset containing cost reports beginning 3 years prior to the fiscal year that is the subject of the rulemaking, because in general it is the most complete full fiscal year of cost report data available at the time of development of the rule. Therefore, for FY 2022 ratesetting, under ordinary circumstances, that would be the HCRIS dataset from FY 2019, which would primarily contain cost reports beginning during FY 2019 and ending during FY 2020, based on each LTCH's fiscal year. In the proposed rule, we discussed that the FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset, however, both contain data significantly impacted by the COVID–19 PHE, meaning primarily the utilization of LTCH services was

generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. To determine whether these data are still the best available data for LTCH PPS ratesetting, we stated that it is important to evaluate whether these data would better approximate the FY 2022 LTCH experience than data from before the COVID–19 PHE.

In section I.F. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25087), we discussed our examination of COVID–19 vaccination data from the CDC to help evaluate whether the FY 2020 data we ordinarily would use in ratesetting is appropriate for approximating the FY 2022 inpatient experience, including in LTCHs. The CDC data showed that as of April 15, the 7-day average number of administered vaccine doses reported to CDC per day was 3.3 million, a 10.3 percent increase from the previous week. As of April 15, 80 percent of people 65 or older had received at least one dose of vaccine; 63.7 percent were fully vaccinated. Nearly one-half (48.3 percent) of people 18 or older had received at least one dose of vaccine; 30.3 percent were fully vaccinated. Nationally, COVID–19-related emergency department visits as well as both hospital admissions and current hospitalizations had risen among patients ages 18 to 64 years in recent weeks, but emergency department visits and hospitalizations among people ages 65 years and older had decreased, likely demonstrating the important role vaccination plays in protecting against COVID–19.

As indicated by the CDC, COVID–19 vaccines are effective at preventing COVID–19. For example, a CDC report on the effectiveness of the Pfizer-BioNTech and Moderna COVID–19 vaccines when administered in real-world conditions found that after being fully vaccinated with either of these vaccines a person's risk of infection is reduced by up to 90 percent. With respect to inpatient utilization in FY 2020, in the proposed rule we stated our belief that COVID–19 and the risk of disease were drivers of the different utilization patterns observed. Therefore, the continuing rapid increase in vaccinations coupled with the overall effectiveness of the vaccines led us to conclude based on the information available at the time of the proposed rule that there will be significantly lower risk of COVID–19 in FY 2022 and fewer hospitalizations for COVID–19 for Medicare beneficiaries in FY 2022 than there were in FY 2020. We concluded that this trend called into question the applicability of inpatient hospital data from FY 2020 to the FY 2022 time period. We refer readers to section I.F. of the preamble of this final rule for the details on this analysis.

In section I.F. of the preamble of the proposed rule, we also discussed CDC guidance to healthcare facilities during the COVID–19 PHE (see *https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html*). In its most recent guidance available at the time of the proposed rule, the CDC described how the COVID–19 pandemic has changed how health care is delivered in the United States, and has affected the operations of healthcare facilities. Effects cited by the CDC include increases in patients seeking care for respiratory illnesses, patients deferring and delaying non-COVID–19 care, disruptions in supply chains, fluctuations in facilities' occupancy, absenteeism among staff because of illness or caregiving responsibilities, and increases in mental health concerns.

In the proposed rule, to investigate the effects cited by the CDC, we compared LTCH claims data from the FY 2020 MedPAR to the FY 2019 MedPAR. Similar to the findings for IPPS claims data, we observed several of the changes cited by the CDC. Overall, in FY 2020 LTCH admissions of LTCH PPS standard Federal payment rate cases declined 13 percent compared to FY 2019. However, LTCH PPS standard Federal payment rate cases for MS–LTC–DRG 177 (Respiratory infections and inflammations with MCC), one of the MS–LTC–DRGs most often associated with the treatment of COVID–19, increased by 47 percent. Its share of total LTCH PPS standard Federal payment rate cases increased from 2.0 percent in FY 2019 to 3.4 percent in FY 2020. We also calculated and compared the aggregate case-mix values for LTCH PPS standard Federal payment rate cases in FY 2019 and FY 2020. For FY 2019 we calculated a case-mix value of 1.257 and for FY 2020 we calculated a case-mix value of 1.283, a relatively large 1-year increase in total case-mix of 2.1 percent. We noted that these observed changes in the LTCH claims data also extend to the cost reports submitted by LTCHs that include the COVID–19 PHE time period, since those cost reports that extend into the COVID–19 PHE are based in part on the discharges that occurred during that time.

After analyzing this issue, in the proposed rule we stated our belief that the utilization patterns reflected in the FY 2020 LTCH claims data were significantly altered by the COVID–19 PHE. We also stated our belief that data from before the COVID–19 PHE will better approximate the FY 2022 LTCH experience for the reasons discussed in section I.F. of the preamble of the proposed rule, including an increase in the number of individuals who are vaccinated against COVID–19. Therefore, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25537), we proposed to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID–19 PHE. For example, we proposed to use the FY 2019 MedPAR claims data and the FY 2018 HCRIS file in situations where we ordinarily would have used the FY 2020 MedPAR and the FY 2019 HCRIS file, respectively.

Comment: The vast majority of commenters were fully supportive of our proposal to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID 19 PHE. A commenter expressed concern that using FY 2019 cost information for establishing the proposed FY 2022 payment rates would lead to payment rates that do not appropriately account for additional costs that LTCHs had to absorb during the PHE and may continue to experience in future years.

Response: We appreciate the commenters' support of our proposal to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID 19 PHE. In response to the commenter who expressed concerns with using FY 2019 cost information for establishing the proposed FY 2022 rates, we appreciate the feedback. However, we believe that the commenter may have misinterpreted what aspects of the FY 2022 ratesetting were impacted by our proposal to use FY 2019 data in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID 19 PHE. The mechanism that CMS uses to adjust the LTCH PPS standard Federal payment rate for input price inflation is the annual market basket update, determined by the Office of the Actuary (OACT). The market basket update values for FY 2022 and prior years were not impacted by our proposal to use FY 2019 data for FY 2022 ratesetting.

Since the publication of the proposed rule, we have continued to monitor the vaccination and hospitalization data reported by the CDC (see *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07022021.html*, accessed July 6, 2021).

As of July 1, 2021, 328.2 million vaccine doses have been administered. Overall, about 181.3 million people, or 54.6 percent of the U.S. population, have received at least one dose of vaccine as of this date. About 155.9 million people, or 47.0 percent of the U.S. population have been fully vaccinated. As of July 1, the 7-day average number of administered vaccine doses reported to CDC per day was 334,816, a 45.3 percent decrease from the previous week. As of July 1, 88.2 percent of people 65 or older have received at least one dose of vaccine; 78.3 percent are fully vaccinated. Two-thirds (66.7 percent) of people 18 or older have received at least one dose of vaccine; 57.7 percent are fully vaccinated. Nationally, the COVID–19-related 7-day moving average for new hospital admissions has been generally decreasing since publication of the proposed rule, demonstrating the important role vaccination is playing in protecting against COVID–19. As of July 3, 2021 (the most recent date with data available at the time of writing), the 7-day moving average for new hospital admissions was 1,821, down significantly from the 7-day moving average peak of 16,492 recorded on January 9th, 2021 and the 7-day moving average of 5,075 recorded on April 27, 2021, the date the proposed rule was issued.[803]

In the proposed rule, we analyzed the large growth in real-case mix observed in the FY 2020 MedPAR claims data. This analysis was consistent with the observations in the CDC's guidance that COVID 19 increased the number of patients seeking care for respiratory illnesses, and caused patients to defer and delay non-COVID–19 care. While we acknowledge that the rate of vaccination for the U.S. population has slowed considerably since we released the proposed rule, the total number of vaccines administered, especially for people 65 or older, along with the latest hospitalization trends, lead us to continue to believe that there will be a significantly lower risk of COVID–19 in FY 2022 and fewer hospitalizations for COVID–19 for Medicare beneficiaries in FY 2022 than there were in FY 2020. For these reasons, we continue to believe that FY 2020 is not the best overall approximation of the LTCH experience in FY 2022 and that FY 2019 as the most recent complete FY prior to the COVID–19 PHE is a better approximation of the FY 2022 LTCH experience.

Therefore, after considering the comments received and evaluating the most recent vaccination and hospitalization data from the CDC, we are finalizing our proposal to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID 19 PHE. For example, we used the FY 2019 MedPAR claims data and the FY 2018 HCRIS file in situations where we ordinarily would have used the FY 2020 MedPAR and the FY 2019 HCRIS file, respectively. This provision is consistent with the provision made for FY 2022 IPPS ratesetting in section I.F. of the preamble of this final rule, and we note that IPPS rates and factors are used in determining the IPPS comparable amount under the short-stay outlier (SSO) policy at § 412.529 and the IPPS comparable amount under the site neutral payment rate at § 412.522. We refer readers to section I.F. of the preamble of this final rule for further information on this provision.

We note that we received several comments, many of which related to the ALOS requirement or requests for other potential revisions to the PPS, which were outside the scope of the proposed rule. We will keep these comments in mind for future rulemaking.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2022

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. For FY 2022, there will be 767 MS–DRG groupings based on the changes, as discussed in section II.E. of the preamble of the final rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. Then we assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In this section of this final rule, we provide a general summary of our existing methodology for determining the FY 2022 MS–LTC–DRG relative weights under the LTCH PPS.

[803] New Admissions of Patients with Confirmed COVID–19., available at *https://covid.cdc.gov/covid-data-tracker-/#new-hospital-administrations* (accessed July 3, 2021).

As we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25538), in general, for FY 2022, we are continuing to use our existing methodology to determine the MS–LTC–DRG relative weights (as discussed in greater detail in section VII.B.3. of the preamble of this final rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, which began in FY 2016, as we proposed, the annual recalibration of the MS–LTC–DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate had been in effect at the time of discharge when claims data from time periods before the dual rate LTCH PPS payment structure applies are used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights (80 FR 49624). That is, under our current methodology, our MS–LTC–DRG relative weight calculations do not use data from cases paid at the site neutral payment rate under § 412.522(c)(1) or data from cases that would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of that discharge. For the remainder of this discussion, we use the phrase ''applicable LTCH cases'' or ''applicable LTCH data'' when referring to the resulting claims data set used to calculate the relative weights (as described in greater detail in section VII.B.3.c. of the preamble of this final rule). In addition, for FY 2022, as we proposed, we are continuing to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VII.B.3.c. of the preamble of this final rule.

Furthermore, for FY 2022, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, as we proposed, we are continuing to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we grouped all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we accounted for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and we made adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VII.B.3.g. of the preamble of this final rule.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using version ASC X12 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162. Among other requirements, on or after January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787

through 56790) and section II.E.1. of the preamble of this final rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS–LTC–DRGs for FY 2022

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this final rule, as we proposed, we updated the MS–LTC–DRG classifications effective October 1, 2021 through September 30, 2022 (FY 2022), consistent with the changes to specific MS–DRG classifications presented in section II.F. of the preamble of this final rule. Accordingly, the MS–LTC–DRGs for FY 2022 presented in section II.F. of the preamble of this final rule are the same as the MS–DRGs that are being used under the IPPS for FY 2022. In addition, because the MS–LTC–DRGs for FY 2022 are the same as the MS–DRGs for FY 2022, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under GROUPER Version 39 as discussed in section II.E. of the preamble of this final rule, including the changes to the MCE software and the ICD–10–CM/PCS coding system, also are applicable under the LTCH PPS for FY 2022.

3. Development of the FY 2022 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

b. Development of the MS–LTC–DRG Relative Weights for FY 2022

In this final rule, as we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25540), we are continuing to use our current methodology to determine the MS–LTC–DRG relative weights for FY 2022, including the continued application of established policies related to: The hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our application of our existing methodology for determining the MS–LTC–DRG relative weights for FY 2022, and we discuss the effects of our policies concerning the data used to determine the FY 2022 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

We generally provide the low-volume quintiles and no-volume crosswalk data previously published in Tables 13A and 13B for each annual proposed and final rule as one of our supplemental IPPS/LTCH PPS related data files that are made available for public use via the internet on the CMS website for the respective rule and fiscal year (that is, FY 2019 and subsequent fiscal years) at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of IPPS Table 11 and to make it easier for the public to navigate and find the relevant data and information used for the development of proposed and final payment rates or factors for the applicable payment year while continuing to furnish the same information the tables provided in previous fiscal years (83 FR 41522). We refer readers to the CMS website for the low-volume quintiles and no-volume crosswalk data previously furnished via Tables 13A and 13B.

c. Data

Ordinarily, for this FY 2022 final rule, we would use FY 2020 Medicare LTCH claims data for purposes of calculating the MS–LTC–DRG relative weights for FY 2022. As discussed in section VIII.A.4. of the preamble of this final rule, we believe the utilization patterns reflected in the FY 2020 LTCH claims data were significantly impacted by the COVID–19 PHE. Therefore, for the purposes of calculating the MS–LTC–DRG relative weights for FY 2022, as we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25540), we used FY 2019 Medicare LTCH claims data from the March 2020 update of the FY 2019 MedPAR file, which we believe are the best available data at this time for the reasons discussed in section VIII.A.4. of the preamble of this final rule. Specifically, for this FY 2022 IPPS/LTCH PPS final rule, as we proposed, we obtained total charges from FY 2019 Medicare LTCH claims data from the March 2020 update of the FY 2019 MedPAR file and used Version 39 of the GROUPER to classify LTCH cases.

To calculate the FY 2022 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, as we proposed, we continued to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the March 2020 update of the FY 2019 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2019 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or
- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2019 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. (We note that, for purposes of developing the MS–LTC–DRG relative weights we have previously addressed the treatment of cases that would have been excluded from the site neutral payment rate under the statutory provisions that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain spinal cord specialty hospitals or for certain severe wound care discharges from certain LTCHs provided by sections 15009 and 15010 of Public Law 114–255, respectively. The temporary exception from the site neutral payment rate for certain spinal cord specialty hospitals is effective for discharges in cost reporting periods beginning during FYs 2018 and 2019, and the temporary exception from the site neutral payment rate for certain severe wound care discharges from certain LTCHs was effective for a discharge in cost reporting period beginning during FY 2018. These statutory provisions will no longer be in effect for any discharges occurring in FY 2022. Therefore, consistent with our historical policy of only using cases that meet the criteria for exclusion from the site neutral payment rate, we excluded these cases in our development of the MS–LTC–DRG relative weights for FY 2022.)

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the MS–LTC–DRG relative weights for FY 2022

In summary, in general, we identified the claims data used in the development of the FY 2022 MS–LTC–DRG relative weights in this final rule, as we proposed, by trimming claims data that were paid the site neutral payment rate or would have been paid the site neutral

payment rate had the dual payment rate structure been in effect. Finally, as we proposed, we trimmed the claims data of all-inclusive rate providers reported in the March 2020 update of the FY 2019 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2020 update of the FY 2019 MedPAR file, but, had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy. As we proposed, we used the remaining data (that is, the applicable LTCH data) to calculate the relative weights for FY 2022.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2022 IPPS/LTCH PPS final rule, as we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25541), we continued to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2022. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2022, as we proposed, we continued to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.B.3.g. (Step 3) of the preamble of this final rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§§ 412.529 and 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio was multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of this final rule) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail in this final rule). For FY 2022, as we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25542), we are continuing to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2022 MS–LTC–DRG relative weights.

In determining the FY 2022 MS–LTC–DRG relative weights, when necessary, as is our longstanding practice, as we proposed, we made adjustments to account for nonmonotonicity, as discussed in greater detail in Step 6 of section VII.B.3.g. of the preamble of this final rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Low-Volume MS–LTC–DRGs

In order to account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, as we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25542), we are continuing to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148).) In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile results in nonmonotonicity within a base-DRG, as we proposed, we made adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VII.B.3.g. (Step 6) of the preamble of this final rule.

In this final rule, based on the best available data (that is, the March 2020 update of the FY 2019 MedPAR files), we identified 251 MS–LTC–DRGs that contained between 1 and 24 applicable

LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles, each containing at least 50 MS–LTC–DRGs (251/5 = 50 with a remainder of 1). We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this final rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, as we proposed, we employed our historical methodology for determining which of the low-volume quintiles would contain the additional low-volume MS–LTC–DRG. Specifically for this final rule, because the average charge of the 51st low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 50th low-volume MS–LTC–DRG (assigned to Quintile 1) than to the average charge of the 52nd low-volume MS–LTC–DRG (assigned to Quintile 2), we assigned it to Quintile 1 (such that Quintile 1 contains 51 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed in this final rule). This resulted in 4 of the 5 low-volume quintiles containing 50 MS–LTC–DRGs (Quintiles 2, 3, 4, and 5) and 1 of the low-volume quintiles containing 51 MS–LTC–DRGs (Quintile 1). As discussed earlier, for this final rule, we are providing the list of the composition of the low-volume quintiles for low-volume MS–LTC–DRGs for FY 2022 in a supplemental data file for public use posted via the internet on the CMS website for this final rule at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

In order to determine the FY 2022 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, as we proposed, we used the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in section VII.B.3.g. of the preamble of this final rule. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the FY 2022 MS–LTC–DRG Relative Weights

In this final rule, as we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25542), we are continuing to use our current methodology to determine the FY 2022 MS–LTC–DRG relative weights.

In summary, to determine the FY 2022 MS–LTC–DRG relative weights, as we proposed, we grouped applicable LTCH cases to the appropriate MS–LTC–DRG, while taking into account the low-volume quintiles (as described previously) and cross-walked no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate MS–LTC–DRG (or low-volume quintile), as we proposed, we calculated the FY 2022 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2). Next, as we proposed, we adjusted the number of applicable LTCH cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases (Step 3). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1) and statistical outliers (Step 2), which are the SSO-adjusted applicable LTCH cases and corresponding charges (Step 3), as we proposed, we calculated ''relative adjusted weights'' for each MS–LTC–DRG (or low-volume quintile) using the HSRV method.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our calculation of the FY 2022 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the FY 2022 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the FY 2022 MS–LTC–DRG relative weights, as we proposed, we removed LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove statistical outliers.

The next step in our calculation of the FY 2022 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, as we proposed, we continued to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this final rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 3—Adjust charges for the effects of SSOs.

As the next step in the calculation of the FY 2022 MS–LTC–DRG relative weights, consistent with our historical approach, as we proposed, we adjusted each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, as we proposed, we made this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the

case to the average length of stay of all cases grouped to the MS–LTC–DRG. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the FY 2022 MS–LTC–DRG relative weights would lower the FY 2022 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, as we proposed, we continued to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the FY 2022 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, as we proposed, we calculated the FY 2022 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculated a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2022 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 3 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 3 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a FY 2022 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS–LTC–DRGs for which there were no claims in the March 2020 update of the FY 2019 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this final rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, as we proposed, we cross-walked each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' MS–LTC–DRG is assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this final rule).

Of the 767 MS–LTC–DRGs for FY 2022, we identified 375 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. This number includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this rule, such that we identified 347 MS–LTC–DRGs that for which, as we proposed, we assigned a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, $375 - 11 - 2 - 15 = 347$). As we proposed, we assigned relative weights to each of the 347 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 392 ($767 - 375 = 392$) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2019 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as one of the 392 MS–LTC–DRGs to which we cross-walked each of the 347 ''no-volume'' MS–LTC–DRGs.) Then, as we generally proposed, we assigned the 347 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG. (As explained in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the March 2020 update of the FY 2019 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2022, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume

MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2022. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2022. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing relative weights.)

As discussed earlier, for this final rule, we are providing the list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2022 in a supplemental data file for public use posted via the internet on the CMS website for this final rule at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the relative weights for the FY 2022 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume MS–LTC–DRGs crosswalk information for FY 2022 (which, as previously stated, we are providing in a supplemental data file posted via the internet on the CMS website for this final rule).

Example: There were no trimmed applicable LTCH cases in the FY 2019 MedPAR file that we are using for this final rule for MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that MS–LTC–DRG 070 (Nonspecific cerebrovascular disorders with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 70 of 0.8732 for FY 2022 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume will vary in the future. Consistent with our historical practice, as we proposed, we used the best available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in the final rule.

For FY 2022, consistent with our historical relative weight methodology, we proposed to establish a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas/Kidney Transplant with Hemodialysis (MS–LTC–DRG 019); Pancreas Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS LTC DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, as we proposed, we established a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, as we proposed, we established a relative weight of 0.0000 for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). As we proposed, we established a relative weight 0.0000 for these 15 ''psychiatric or rehabilitation'' MS LTC DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate will not be applicable for any LTCH discharges occurring in FY 2022, and as such payment under the LTCH PPS will be no longer be made in part based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–DRGs.

Step 6—Adjust the FY 2022 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-

level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the FY 2022 MS–LTC–DRG relative weights, consistent with our historical methodology, as we proposed, we continued to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the FY 2022 MS–LTC–DRG relative weights in this final rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website.

Step 7—Calculate the FY 2022 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the best available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, as we proposed, we updated the MS–LTC–DRG classifications and relative weights for FY 2022 based on the best available LTCH data for applicable LTCH cases, and continued to apply a budget neutrality adjustment in determining the FY 2022 MS–LTC–DRG relative weights.

In this final rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), as we proposed, we continued to use our established two-step budget neutrality methodology.

To calculate the normalization factor for FY 2022, as we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25546), we grouped applicable LTCH cases using the FY 2022 Version 39 GROUPER, and the recalibrated FY 2022 MS–LTC–DRG relative weights to calculate the average case-mix index (CMI); we grouped the same applicable LTCH cases using the FY 2021 GROUPER Version 38 and MS–LTC–DRG relative weights and calculated the average CMI; and computed the ratio by dividing the average CMI for FY 2021 by the average CMI for FY 2022. That ratio is the normalization factor. Because the calculation of the normalization factor involves the relative weights for the MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume MS–LTC–DRGs are included in the calculation (and the MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation).

To calculate the budget neutrality adjustment factor, we simulated estimated total FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2022 normalized relative weights and GROUPER Version 39; simulated estimated total FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2021 MS–LTC–DRG relative weights and the FY 2021 GROUPER Version 38; and calculated the ratio of these estimated total payments by dividing the simulated estimated total LTCH PPS standard Federal payment rate payments using the FY 2021 MS–LTC–DRG relative weights and the GROUPER Version 38 by the simulated estimated total LTCH PPS standard Federal payment rate payments using the FY 2022 MS–LTC–DRG relative weights and the GROUPER Version 39. The resulting ratio is the budget neutrality adjustment factor. The calculation of the budget neutrality factor involves the relative weights for the LTCH cases used in the payment simulation, which includes any cases grouped to low-volume MS–LTC–DRGs, and generally does not include payments for cases grouped to a MS–LTC–DRG with no applicable LTCH cases. Occasionally, a few LTCH cases (that is, those with a covered length of stay of 7 days or less), which are removed from the relative weight calculation in step 2 that are grouped to a MS–LTC–DRG with no applicable LTCH cases are included in the payment simulations used to calculate the budget neutrality factor. However, the number and payment amount of such cases have a negligible impact on the budget neutrality factor calculation.

In this final rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), as we proposed, we continued to use our established two-step budget neutrality methodology. Therefore, in this final rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2022, as we proposed, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2022 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) Use the applicable LTCH cases from the best available data (that is, LTCH discharges from the FY 2019 MedPAR file) and group them using the FY 2022 GROUPER (that is, Version 39 for FY 2022) and the recalibrated FY 2022 MS–LTC–DRG relative weights (determined in Steps 1 through 6 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2021 GROUPER (Version 38) and FY 2021 MS–LTC–DRG relative weights and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average CMI for FY 2021 (determined in Step 1.b.) by the average case-mix index for FY 2022 (determined in Step 1.a.). As a result, in determining the MS–LTC–DRG relative weights for FY 2022, each recalibrated MS–LTC–DRG relative weight is multiplied by the normalization factor of 1.25815 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our MS–LTC–DRG budget neutrality methodology, we calculated a second budget neutrality factor consisting of the ratio of estimated aggregate FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.b. stated previously) before reclassification and recalibration to estimated aggregate payments for FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases after reclassification and recalibration (that is, the sum of all calculations under Step 1.a. stated previously).

That is, for this final rule, for FY 2022, under the second step of the budget neutrality methodology, as we proposed, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) Simulate estimated total FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the normalized relative weights for FY 2022 and GROUPER Version 39 (as described previously); (2.b.) simulate estimated total FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2021 GROUPER (Version 38) and the FY 2021 MS–LTC–DRG relative weights in Table 11 of the FY 2021 IPPS/LTCH PPS final rule available on the internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the FY 2022 MS–LTC–DRG relative weights, each normalized relative weight is then multiplied by a budget neutrality factor of 1.0002384 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the FY 2022 MS–LTC–DRG relative weights in this final rule, consistent with our existing methodology, as we proposed, we applied a normalization factor of 1.25815 and a budget neutrality factor of 1.0002384. Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2022.

C. Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2022

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and § 412.535. In this section, we discuss the factors that we used to update the LTCH PPS standard Federal payment rate for FY 2022, that is, effective for LTCH discharges occurring on or after October 1, 2021 through September 30, 2022. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at 42 CFR 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate (FYs 2003 through 2015)/LTCH PPS standard Federal payment rate (FY 2016 through present) as implemented under 42 CFR 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2022 IPPS/LTCH PPS final rule, we present our policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2022.

The update to the LTCH PPS standard Federal payment rate for FY 2022 is presented in section V.A. of the Addendum to this final rule. The components of the annual update to the LTCH PPS standard Federal payment rate for FY 2022 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2022 as required by the statute (as discussed in section VIII.C.2.c. of the preamble of this final rule). As we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25547), we also made an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2022 on estimated aggregate LTCH PPS payments, in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule). (We note that in the FY 2022 IPPS/LTCH PPS proposed rule, we did not make any proposals which would change the FY 2022 LTCH PPS standard Federal payment rate that are based on the elimination of the 25-percent threshold policy because the permanent, one-time factor was proposed and adopted in the FY 2021 IPPS/LTCH PPS Final Rule for FY 2021 and subsequent years (85 FR 58907)).

2. FY 2022 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2017-based LTCH market basket for

use under the LTCH PPS beginning in FY 2021 (85 FR 58907 through 58909). For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2022

CMS has used an estimated market basket increase to update the LTCH PPS. As previously noted, we adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021. The 2017-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. (For additional details on the development of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).)

In the FY 2021 IPPS/LTCH final rule, we finalized the price proxies for the 2017-based LTCH market basket. In that final rule, we established the use of the Moody's AAA Corporate Bond Yield index as the price proxy for the For-profit Interest cost category (85 FR 58919). Effective for December 2020, the Moody's AAA Corporate Bond series is no longer available for use under license to IGI, the nationally-recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets productivity adjustment. In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to use the iBoxx AAA Corporate Bond Yield index instead of the Moody's AAA Corporate Bond Yield index in the 2017-based LTCH market basket. We stated that because the iBoxx AAA Corporate Bond Yield index captures the same technical concept as the current corporate bond proxy and tracks similarly to the current measure that is no longer available, we believe that using the iBoxx AAA Corporate Bond Yield index is technically appropriate to use in the 2017-based LTCH market basket (86 FR 25558). We did not receive any comments on the proposed change to the price proxy for the AAA Corporate Bond Yield index for the for-profit cost category. Therefore, we are finalizing the use of the iBoxx AAA Corporate Bond Yield index for use in the 2017-based LTCH market basket as proposed.

We continue to believe that the 2017-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2021 IPPS/LTCH PPS final rule. Therefore, in this final rule, as we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25548), we used the 2017-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2022.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A), as applicable. Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, ''the productivity adjustment''). We note that effective with FY 2022 and forward, CMS is changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We note that this is not a change in policy as the methodology for deriving the adjustment relies on the same underlying data and methodology. This change in terminology results in a title more consistent with the statutory language described in section 1886(b)(3)(B)(xi)(II) of the Act. Clause (ii) of section 1886(m)(3)(A) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act; therefore, it is not applicable for FY 2022.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under 42 CFR 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (42 CFR 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at 42 CFR 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this final rule.)

d. Annual Market Basket Update Under the LTCH PPS for FY 2022

Consistent with our historical practice, we estimate the market basket increase and the productivity adjustment based on IGI's forecast using the most recent available data. Based on IGI's fourth quarter 2020 forecast, the proposed FY 2022 full market basket estimate for the LTCH PPS using the 2017-based LTCH market basket was 2.4 percent. The proposed productivity adjustment for FY 2022 based on IGI's fourth quarter 2020 forecast was 0.2 percent.

For FY 2022, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25548), to reduce the full estimated FY 2022 market basket increase by the FY 2022 productivity adjustment. To determine the proposed market basket increase for LTCHs for FY 2022, as reduced by the proposed productivity adjustment, consistent with our established methodology, we subtracted the proposed FY 2022 productivity adjustment from the estimated FY 2022 market basket increase. (For additional details on our established methodology for adjusting the market basket increase by the productivity adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2022, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, the proposed 2.4 percent update to the LTCH PPS standard Federal payment rate for FY 2022 would be reduced by the 0.2 percentage point productivity adjustment as required under section 1886(m)(3)(A)(i) of the Act and the additional 2.0 percentage points reduction required by section 1886(m)(5) of the Act.

In the FY 2022 IPPS/LTCH PPS proposed rule, in accordance with the statute, we proposed to reduce the proposed FY 2022 full market basket estimate of 2.4 percent (based on IGI's fourth quarter 2020 forecast of the 2017-based LTCH market basket) by the proposed FY 2022 productivity adjustment of 0.2 percentage point (based on IGI's fourth quarter 2020 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we proposed to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2022 of 2.2 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 2.4 percent less the productivity adjustment of 0.2 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), we proposed to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we proposed to establish an annual update to the LTCH PPS standard Federal payment rate of 0.2 percent (that is, 2.2 percent minus 2.0 percentage points) for FY 2022 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25549), to use a more recent estimate of the market basket and the productivity adjustment, if appropriate, in the final rule to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2022. (We note that, consistent with historical practice, we also proposed to adjust the FY 2022 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to the proposed rule).

We did not receive any comments on the proposed LTCH market basket update or the productivity adjustment. Therefore, we are finalizing the LTCH payment update using the most recent forecast of the market basket and productivity adjustment. As such, based on IGI's second quarter 2021 forecast, the FY 2022 full market basket estimate for the LTCH PPS using the 2017-based LTCH market basket is 2.6 percent. The current estimate of the productivity adjustment for FY 2022 based on IGI's second quarter 2021 forecast is 0.7 percent. Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we are establishing an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2022 of 1.9 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 2.6 percent less the productivity adjustment of 0.7 percentage point).

For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), as we proposed, we further reduced the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are establishing an annual update to the LTCH PPS standard Federal payment rate of −0.1 percent (that is, 1.9 percent minus 2.0 percentage points) for FY 2022 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP.

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

In section IX. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25549 through 25628), we sought public comment on two focus areas, and also proposed changes to the Medicare quality reporting systems:

- In section IX.A., advancing to digital quality measurement and the use of Fast Healthcare Interoperability Resources (FHIR) in hospital quality programs;
- In section IX.B., closing the health equity gap in CMS hospital quality programs;
- In section IX.C., the Hospital IQR Program;
- In section IX.D., the PCHQR Program; and
- In section IX.E., the LTCH QRP.

In addition, in section IX.F. of the preamble of that proposed rule (86 FR 25628 through 25654), we proposed changes to the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs) for eligible hospitals and critical access hospitals (CAHs).

A. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs—Request for Information

We aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. As part of this modernization of our quality measurement enterprise, we issued a request for information (RFI). The purpose of this RFI was to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to

specific program requirements related to providing data for quality measurement and reporting provisions will be addressed through future rulemaking, as necessary. The RFI contained five parts:

- Background. This part provides information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provides a summary of recent HHS policy developments that are advancing interoperability and could support our move towards full digital quality measurement.
- Definition of Digital Quality Measures (dQMs). This part provides a potential definition for dQMs. Specific requests for input are included in the section.
- Use of Fast Healthcare Interoperability Resources (FHIR®) for current electronic clinical quality measures (eCQMs). This part provides information on current activities underway to align CMS eCQMs with the FHIR standard and support quality measurement via application programming interfaces (APIs), and contrasts this approach to current eCQM standards and practice.
- Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025. This part introduces four possible steps that would enable transformation of CMS' quality measurement enterprise to be fully digital by 2025. Specific requests for input are included in the section.
- Solicitation of Comments. This part lists all requests for input included in the sections of this RFI.

1. Background

As required by law, we implement quality measurement and value-based purchasing programs across a broad range of inpatient acute care, outpatient, and post-acute care (PAC) settings consistent with our mission to improve the quality of health care for Americans through measurement, transparency, and increasingly, value-based purchasing. These quality programs are foundational for incentivizing value-based care, contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2017, we launched the Meaningful Measures Framework. This framework for quality measurement captures our vision to better address health care quality priorities and gaps, including emphasizing digital quality measurement, reducing measurement burden, and promoting patient perspectives, while also focusing on modernization and innovation. The scope of the Meaningful Measures Framework evolves as the health care environment continues to change.[804] Consistent with the Meaningful Measures Framework, we aim to move fully to digital quality measurement by 2025. We acknowledge providers within the various care and practice settings covered by our quality programs may be at different stages of readiness, and therefore, the timeline for achieving full digital quality measurement across our quality reporting programs may vary.

We also continue to evolve the Medicare Promoting Interoperability Program's focus on the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement (83 FR 41634). However, reporting data for quality measurement via EHRs remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).[805] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

Additionally, advancements in technical standards and associated regulatory initiatives to improve interoperability of healthcare data are creating an opportunity to significantly improve our quality measurement systems. In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule (85 FR 25510) to support beneficiary access to data held by certain payers. At the same time, the Office of the National Coordinator for Health Information Technology (ONC) finalized policies in the ONC 21st Century Cures Act final rule (85 FR 25642) to advance the interoperability of health information technology (IT) as defined in section 4003 of the Cures Act, including the ''complete access, exchange, and use of all electronically accessible health information.'' Closely working with ONC, we collaboratively identified Health Level 7 (HL7®) FHIR Release 4.0.1 as the standard to support Application Programming Interface (API) policies in both rules. ONC, on behalf of HHS, adopted the HL7 FHIR Release 4.0.1 for APIs and related implementation specifications at 45 CFR 170.215. We believe the FHIR standard has the potential to be a more efficient and modular standard to enable APIs. We also believe this standard enables collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost. By aligning technology requirements for payers, health care providers, and health IT developers HHS can advance an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

In the ONC 21st Century Cures Act final rule, ONC adopted a ''Standardized API for Patient and Population Services'' certification criterion for health IT that requires the use of FHIR Release 4 and several implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742).[806] The ONC 21st Century Cures Act final rule also requires health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard.[807] The scope of patient data identified in the USCDI and the data standards that support this data set are expected to evolve over time, starting with data specified in Version 1 of the USCDI. In November 2020, ONC issued an interim final rule with comment period extending the date when health IT developers must make technology meeting updated certification criteria available under the ONC Health IT Certification Program until December 31, 2022 (85 FR 70064).[808]

The CMS Interoperability and Patient Access final rule (85 FR 25510) and program policies build on the ONC 21st Century Cures Act final rule (85 FR 25642). The CMS Interoperability and Patient Access final rule and policies require certain payers (for example, Medicare Advantage organizations, Medicaid and CHIP Fee-for-Service programs, Medicaid managed care plans, CHIP managed care entities, and issuers of certain Qualified Health Plan

[804] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[805] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data.*

[806] Application Programming Interfaces (API) Resource Guide, Version 1.0. Available at: *https://www.healthit.gov/sites/default/files/page/2020-11/API-Resource-Guide_v1_0.pdf.*

[807] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[808] Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid–19 Public Health Emergency. Available at: *https://www.govinfo.gov/content/pkg/FR–2020-11-04/pdf/2020-24376.pdf.*

[QHP] on the Federally-facilitated Exchanges [FFEs]) to implement and maintain a standards-based Patient Access API using HL7 FHIR Release 4.0.1 to make available certain data to their enrollees and beneficiaries (called ''patients'' in the CMS interoperability rule). These certain data include data concerning claims and encounters, with the intent to ensure access to their own health care information through third-party software applications. The rule also established new Conditions of Participation for Medicare and Medicaid participating hospitals and critical access hospitals (CAHs), requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred (85 FR 25603). In the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84472), we finalized a policy to align the certified EHR technology required for use in the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category with the updates to health IT certification criteria finalized in the ONC 21st Century Cures Act final rule. Under this policy, MIPS eligible clinicians, and eligible hospitals and CAHs participating in the Promoting Interoperability Programs, must use technology meeting the updated certification criteria for performance and reporting periods beginning in 2023 (85 FR 84825).

The use of APIs can also reduce long-standing barriers to quality measurement. Currently, health IT developers are required to implement individual measure specifications within their health IT products. The health IT developer must also accommodate how that product connects with the unique variety of systems within a specific care setting.[809] This may be further complicated by systems that integrate a wide range of data schemas. This process is burdensome and costly, and it is difficult to reliably obtain high quality data across systems. As health IT developers map their health IT data to the FHIR standard and related implementation specifications, APIs can enable these structured data to be easily accessible for quality measurement or other use cases, such as care coordination, clinical decision support, and supporting patient access.

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025, and are committed to exploring and seeking input on potential solutions for the transition to digital quality measurement as described in this RFI.

2. Definition of Digital Quality Measures

In the proposed rule, we sought to refine the definition of digital quality measures (dQMs) to further operationalize our objective of fully transitioning to dQMs by 2025. We previously noted dQMs use ''sources of health information that are captured and can be transmitted electronically and via interoperable systems'' (85 FR 84845). In this RFI, we sought input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. We also noted that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs.

We discuss one potential approach to developing dQM software in section IX.A.4.b. of the preamble of this final rule. In this section, we sought comment on the potential definition of dQMs in this RFI.

We also sought feedback on how leveraging advances in technology (for example, FHIR APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).

The transition to dQMs relies on advances in data standardization and interoperability. As providers and payers work to implement the required advances in interoperability over the next several years, we will continue to support reporting of eCQMs through CMS quality reporting programs and through the Promoting Interoperability programs.[810] These fully digital measures continue to be important drivers of interoperability advancement and learning. As discussed in the next section, CMS is currently re-specifying and testing these measures to use FHIR rather than the currently adopted Quality Data Model (QDM) in anticipation of the wider use of FHIR standards. CMS intends to apply significant components of the output of this work, such as the re-specified measure logic and the learning done through measure testing with FHIR APIs, to define and build future dQMs that take advantage of the expansion of standardized, interoperable data.

3. Use of FHIR for Current eCQMs

Since we adopted eCQMs in our hospital and clinician quality programs, we have heard from stakeholders about the technological challenges, burden, and related costs of reporting eCQM data. The CMS eCQM Strategy Project engaged with stakeholders through site visits and listening sessions with health systems and provider organizations to learn about their experiences. This stakeholder feedback identified recommendations to improve processes related to alignment; development; implementation and reporting; certification; and communication, education, and outreach. Over the past two years, we have focused on opportunities to streamline and modernize quality data collection and reporting processes, such as exploring FHIR® (*http://hl7.org/fhir*) as a framework for measure structure and data submission for quality reporting programs, specifically for eCQMs. FHIR is a free and open source standards framework (in both commercial and government settings) created by Health Level Seven International (HL7®) that establishes a common language and process for all health information technology. FHIR allows systems to communicate and information to be shared seamlessly, with a lower burden for hospitals, providers, clinicians, vendors, and quality measurement stakeholders. Specifically, for quality reporting, FHIR enables representing the data in eCQMs as well as provides a structure for eCQMs and reporting, using FHIR as the standard for all. Whereas today, multiple standards being used to report eCQMs is challenging and burdensome.

We are working to convert current eCQMs to the FHIR standard. We are currently testing the exchange of data elements represented in FHIR to CMS

[809] The Office of the National Coordinator for Health Information Technology, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Final Report (Feb. 2020). Available at: *https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.*

[810] eCQI Resource Center, *https://ecqi.healthit.gov/.*

through ongoing HL7 Connectathons and integrated system testing by using and refining implementation guides. Submitting data through FHIR APIs has the potential to improve data exchange by providing consistent security, performance, scalability, and structure to all users. In addition, development of FHIR APIs could decrease provider burden by automating more of the measure data collection process. We continue to explore and expand potential applications of the FHIR standard and testing with eCQM use cases, and we are considering a transition to FHIR-based quality reporting with the use of the FHIR standard for eCQMs in quality and value-based reporting programs. As we move to an all-dQM format for quality programs, we are depending on testing results and community readiness to improve interoperability, reduce burden, and facilitate better patient care. We will continue to consider how to leverage the interoperability advantages offered by the FHIR standards and API-based data submission, including digital quality measurement.

4. Changes Under Consideration To Advance Digital Quality Measurement: Potential Actions in Four Areas to Transition to Digital Quality Measures by 2025

Building on the advances in interoperability and learning from testing of FHIR-converted eCQMs, we aim to move fully to dQMs, originating from sources of health information that are captured and can be transmitted electronically via interoperable systems, by 2025.

To enable this transformation, we are considering further modernization of the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion. Data collection and reporting efforts would become more efficient, supported by advances in interoperability and data standardization. Aggregation of data from multiple sources would allow assessments of costs and outcomes to be measured across multiple care settings for an individual patient or clinical conditions. We believe that aggregating data for measurement can incorporate a more holistic assessment of an individual's health and health care and produce the rich set of data needed to enable patients and caregivers to make informed decisions by combining data from multiple sources (for example, patient reported data, EHR data, and claims data) for measurement.

Perhaps most importantly, these steps would help us deliver on the full promise of quality measurement and drive us toward a learning health system that transforms healthcare quality, safety, and coordination and effectively measures and achieves value-based care. The shift from a static to a learning health system hinges on the interoperability of healthcare data, and the use of standardized data. dQMs would leverage this interoperability to deliver on the promise of a learning health system wherein standards-based data sharing and analysis, rapid-cycle feedback, and quality measurement and incentives are aligned for continuous improvement in patient-centered care. Similarly, standardized, interoperable data used for measurement can also be used for other use cases, such as clinical decision support, care coordination and care decision support, which impacts health care and care quality.

We requested comments on four potential future actions that would enable transformation to a fully digital quality measurement enterprise by 2025.

a. Leveraging and Advancing Standards for Digital Data and Obtaining all EHR Data Required for Quality Measures via Provider FHIR-Based APIs

We are considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data. Utilizing standardized data for EHR-based measurement (based on FHIR and associated implementation guides) and aligning where possible with interoperability requirements can eliminate the data collection burden providers currently experience with required chart-abstracted quality measures and reduce the burden of reporting digital quality measure results. We can fully leverage this advance to adapt eCQMs and expand to other dQMs through the adoption of interoperable standards across other digital data sources. We are considering methods and approaches to leverage the interoperability data requirements for APIs in certified health IT set by the ONC 21st Century Cures Act final rule to support modernization of CMS quality measure reporting. As discussed previously, these requirements will be included in certified technology in future years (85 FR 84825) including availability of data included in the USCDI via standards-based APIs, and CMS will require clinicians and hospitals participating in MIPS and the Promoting Interoperability Programs, respectively, to transition to use of certified technology updated consistent with the 2015 Cures Edition Update (85 FR 84825).

Digital data used for measurement could also expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs. Many important data sources are not currently captured digitally, such as survey and PGHD. We intend to work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and administrative claims. Agreed upon standards for these data, and associated implementation guides will be important for interoperability and quality measurement. We will consider developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, requirements for expressing data in standards, exposing data via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability.

High quality data are also essential for reliable and valid measurement. Hence, in implementing the shift to collect all clinical EHR data via FHIR-based APIs, we would support efforts to strengthen and test the quality of the data obtained through FHIR-based APIs for quality measurement. We currently conduct audits of electronic data submitted to the Hospital IQR Program with functions including checks for data completeness and data accuracy, confirmation of proper data formatting, alignment with standards, and appropriate data cleaning (82 FR 38398 through 38402). These functions would continue and be applied to dQMs and further expanded to automate the manual validation of the data compared to the original data source (for example, the medical record) where possible. Analytic advancements such as natural language processing, big data analytics, and artificial intelligence, can support this evolution. These techniques can be applied to validating observed patterns in data and inferences or conclusions

drawn from associations, as data are received, to ensure high quality data are used for measurement.

We sought feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We also sought feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcomed comment on approaches for testing data quality and validity.

b. Redesigning Quality Measures To Be Self-Contained Tools

We are considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s), and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:

- Have the flexibility to support calculation of single or multiple quality measure(s).
- Perform three functions—

++ Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD);

++ Calculate the measure score according to measure logic; and

++ Generate measure score report(s).

- Be compatible with any data source systems that implement standard interoperability requirements.
- Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
- Be tested and updated independently of the data source systems.
- Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
- Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
- Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
- Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.
- Be designed to support pro-competitive practices for development, maintenance, and implementation as well as diffusion of quality measurement and related quality improvement and clinical tools through, for example, the use of open-source core architecture.

We sought comment on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the possible expanding availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs).

We were also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research.

c. Building a Pathway to Data Aggregation in Support of Quality Measurement

Using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, we are considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Qualified Clinical Data Registries and Qualified Registries that report quality measures for eligible clinicians in the Merit-based Incentive Payment System (MIPS) program are potential examples[811] at 42 CFR 414.1440(b)(2)(iv) and (v) and 414.1440(c)(2)(iii) and (iv) and can also support measure reporting. We are considering establishing similar policies for third-party aggregators to maintain the integrity of our measure reporting process and to encourage market innovation.

We sought feedback on aggregation of data from multiple sources to inform measurement and potential policy considerations. We also sought feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation.

d. Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement. We are considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. We would coordinate closely with quality measure developers, Federal and State agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and State agencies and payers to the extent possible.

We intend for this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, disparities, and care coordination), and track with the transformation of data collection, alignment with health IT module updates including capabilities and standards adopted by ONC (for example, standards to enable APIs). This coordination would build on the principles outlined in HHS' National Health Quality Roadmap.[812] It would focus on the quality domains of safety,

[811] Calendar Year (CY) 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1362/QCDR%20and%20QR%20Updates%202021%20Final%20Rule%20Fact%20Sheet.pdf.*

[812] Department of Health and Human Services, National Health Quality Roadmap (May 2020). Available at: *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (Department of Defense and Veterans Affairs [DoD/VA]); the Agency for Healthcare Research and Quality's Clinical Decision Support Initiative; the Centers for Disease Control and Prevention's Adapting Clinical Guidelines for the Digital Age initiative; Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, National Quality Forum (NQF), provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal, State, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements for measures as well as the requirements of other agencies and payers.

We sought feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards). We also sought to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors.

5. Solicitation of Comments

We sought input on the future development of the following:

- Definition of Digital Quality Measures. We sought feedback on the following as described in section IX.A.2. of the preamble of this final rule:

++ Do you have feedback on the dQM definition?

++ Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcomed more specific comments on the attributes or functions to support such an approach of deploying dQMs.

- Use of FHIR for Current eCQMs. We sought feedback on the following as described in section IX.A.3. of the preamble of this final rule:

++ Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT vendors and providers?

++ Would access to near real-time quality measure scores benefit your practice?

++ What parts of the current CMS QRDA IGs cause the most burden?

++ What could we include in a CMS FHIR Reporting IG to reduce burden on providers and vendors?

- Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.

++ We sought feedback on the following as described in section IX.A.4.a. of the preamble of this final rule:

—Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR Implementation Guides suggested for consideration?

—How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

—What are possible approaches for testing data quality and validity?

++ We sought feedback on the following as described in section IX.A.4.b. of the preamble of this final rule:

—What functionalities, described in Section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?

—How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

++ We sought feedback on the following as described in section IX.A.4.c. of the preamble of this final rule:

—Do you have feedback on policy considerations for aggregation of data from multiple sources being used to inform measurement?

—Do you have feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

++ We sought feedback on the following as described in section IX.A.4.d. of the preamble of this final rule:

—What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?

—We also sought to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

We recommended commenters consider provisions in the CMS Interoperability and Patient Access final rule (85 FR 25510), CMS CY 2021 PFS final rule (85 FR 84472), and the ONC 21st Century Cures Act final rule (85 FR 25642).

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. While we will not be responding to specific comments submitted in response to this RFI in this FY 2022 IPPS/LTCH PPS final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

We received comments on these topics.

Comment: There was widespread support among commenters for digital quality measurement. Several commenters supported CMS' transition to digital quality measurement. Several commenters noted that implementing FHIR would simplify the measure reporting process and produce more timely and actionable information. They also expressed support for transitioning to dQMs to reduce reliance on manual processes. Some comments welcomed the use of FHIR in light of the COVID–19 PHE and highlighted the need for harmonized data to quickly share important information.

However, most commenters questioned the feasibility of the proposed 2025 implementation timeline. Some commenters noted the timeline is ambitious. Some commenters provided feedback on what CMS could provide as it transitions to digital quality measurement. Commenters also stated that this process would be resource intensive for providers and healthcare systems. Commenters highlighted that measures have not been selected and recommended that measure specifications should be made available in a timely manner to reduce provider and hospital administrative burden. Within this context, they recommended that measures be vetted by stakeholders, field tested, and validated, and some commenters also suggested endorsement by the National Quality Forum (NQF). In addition, several commenters requested specialty-specific implementation guides.

Several commenters were concerned by the lack of accepted standards for social determinants of health (SDOH) data and potential data quality issues when mapping data from multiple sources. Other commenters expressed concern that dQMs could become a measure of vendor capabilities rather than quality of care.

Some commenters did not support implementing FHIR. Some commenters expressed concern regarding the maturity of the FHIR standard for quality measurement reporting, versioning, and industry readiness to implement FHIR. They recommended that CMS support existing efforts of healthcare providers and health IT vendors to develop and implement interoperability, many of which are based on non-FHIR standards.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25550), we clarified a potential future definition of dQMs as a software that processes digital data to produce a measure score or measure scores.

Comment: Several commenters appreciated CMS' clarifications of the dQM definition. Some commenters supported the potential definition of dQMs and appreciated that CMS is thinking broadly. A commenter lauded the potential definition, noting the payoff would be richer data and measures that could facilitate use of artificial intelligence and real-time reporting.

Other commenters stated that the potential definition is too broad to be meaningful and that it lacks clarity. Within this context, some commenters requested a more formal definition of dQMs and of terms used by CMS, such as patient portals or health information exchanges or registries. They also asked for examples to illustrate how dQMs could be used for quality improvement. Some commenters suggested refinements to the potential definition. A couple of commenters noted that dQMs should be viewed as a framework and that the word ''software'' in the potential definition is confusing as it does not align with the current structure of a quality measure.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

As noted above, we requested input on the use of FHIR for eCQMs and actions in four areas to transition to dQMs by 2025 including:

(1) Leveraging and advancing standards for digital data and obtaining all EHR data required for quality measures via provider FHIR-based APIs.

(2) Redesigning quality measures to be self-contained tools.

(3) Building a pathway to data aggregation in support of quality measurement.

(4) Potential future alignment of measures across reporting programs, Federal and state agencies, and the private sector.

Comment: Several commenters supported CMS' efforts to use data from different sources. The commenters noted capturing data through traditional and emerging sources, including patient-generated health data, could provide a comprehensive picture of patient outcomes, quality, and value. Further, some commenters noted the ability of dQMs to use multiple data sources could reduce administrative burden. However, others pointed out that the list includes several data sources, such as patient wearables, that have not been adequately vetted and tested.

Several commenters noted the importance of data quality. Some commenters raised concerns that the accuracy and reliability of dQMs could be compromised by poor data quality. They recommended CMS consider the development of source system verification and/or certification criteria.

Others noted the importance of reliable and accurate patient matching to ensure interoperability. They recommended using a universal patient identifier to allow for the matching of patient records when derived from different sources.

Several commenters stated that using a multitude of data sources will increase the burden and costs associated with measure development and testing. Some commenters raised a concern that not all data are captured in such a way that it can be pulled via FHIR API. For example, radiology or lab reports are scanned into the EHR system.

Most commenters expressed general support for FHIR-based APIs for quality measurement and agreed the approach will eventually reduce complexity and ease reporting burden over time. Some commenters suggested specific FHIR Implementation Guides for use, or modifying or expanding existing ones.

However, several commenters expressed concerns about the use of FHIR-based APIs such as the infrastructure and financial readiness, providers' unfamiliarity with FHIR, and governance of collecting raw digital data, and data stewardship. Some commenters were concerned the transition period will place increased burden on health systems and providers. In addition, they noted that some health systems or practices may not have the infrastructure in place or the financial capability to develop, test, and implement dQMs. A commenter pointed out that pediatricians are limited by EHR functionality that focuses on adults. These commenters expressed support for a timeline that accounts for various stages of readiness across health sectors and specialties.

Some commenters agreed with redesigning quality measures as self-contained tools and agreed with their functionalities necessary to achieve digital quality measurement. They noted it would be beneficial to those with less technical support. Other commenters requested clarification on the tools and plans for validating digital measures.

Several commenters commented on current limitations for aggregation such as reliable patient-matching, opportunities for data aggregation by third-parties, and steps CMS could take to enable aggregation, such as mandating standards or playing the role

of an aggregator. Some commenters stated that CMS should leverage existing infrastructure, such as HIEs, to support quality measurement and reporting, and real-time information sharing, while other commenters supported CMS serving as a data aggregator to ensure consistency and accuracy in quality measure reporting.

Commenters expressed support for alignment of measurement areas, specifications, data elements used to build the specifications, and tools across reporting programs. Commenters applauded CMS working with stakeholders on aligning data needed for quality measurement with interoperability requirements, and some commenters requested clarification about the role of stakeholders in the process. Commenters also noted alignment could leverage data routinely captured during and across the continuum of clinical care, simplify quality reporting, reduce challenges associated with managing various standards and formats, support other use cases such as clinical decision support, and ultimately help achieve health equity.

Several commenters supported the development of a common dQM portfolio. Some commenters suggested CMS use a common dQM portfolio as the framework of the ongoing transition to digital quality measurement, such as aligning data standards with priority areas in the portfolio. Some commenters encouraged CMS to identify which existing measures could be used as dQMs while concurrently identifying future priority areas. Another commenter noted CMS should implement dQMs that provide clinically meaningful data within one setting even if the dQMs are not ready to be used in other programs. This could encourage dQM implementation and could help enable implementation in other settings. On the other hand, a commenter suggested CMS align with HHS strategic priorities rather than a common dQM portfolio.

Many commenters encouraged CMS to work with the ONC on data and interoperability standards, and relevant certification criteria for EHR technology. Commenters indicated that data elements should be consistent with the United States Core Data for Interoperability (USCDI) wherever possible, with a commenter noting that this is ''critical''.

Some commenters noted additional areas of focus or alignment opportunities for CMS. For example, some commenters noted the importance of standardizing SDOH reporting requirements or high-cost conditions. Others encouraged CMS to develop an immunization registry, noting both the importance of immunizations and the profound disparities in immunization rates across racial and ethnic groups as recognized through the COVID–19 pandemic.

Several commenters supported a phased approach to dQM implementation. Several commenters requested CMS allow adequate time for implementation, testing, and validation to ensure successful transition to dQMs. Some commenters suggested CMS focus first on aligning data standards, then tools and measure requirements. Some commenters also urged CMS to consider pilot opportunities, program incentives, or flexibilities in reporting. A commenter requested that CMS consider alignment with the Interoperability and Patient Access final rule. Another commenter urged CMS to consider the impact of alignment on underserved communities and patients.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

B. Closing the Health Equity Gap in CMS Hospital Quality Programs—Request for Information

Persistent inequities in health care outcomes exist in the United States, including among Medicare patients. In recognition of persistent health disparities and the importance of closing the health equity gap, we request information on revising several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for hospitals, providers, and patients. The following is part of an ongoing effort across CMS to evaluate appropriate initiatives to reduce health disparities. Feedback will be used to inform the creation of a future, comprehensive, RFI focused on closing the health equity gap in CMS programs and policies.

This RFI contains four parts:

- *Background.* This section provides information describing our commitment to health equity, and existing initiatives with an emphasis on reducing health disparities.
- *Current CMS Disparity Methods.* This section describes the methods, measures, and indicators of social risk currently used with the CMS Disparity Methods.
- *Future potential stratification of quality measure results by race and ethnicity.* This section describes three potential future expansions of the CMS Disparity Methods, including (a) Future Potential Stratification of Quality Measure Results by Race and Ethnicity, (b) Improving Demographic Data Collection, and (c) Potential Creation of a *Hospital Equity Score* to Synthesize Results Across Multiple Social Risk Factors.
- *Solicitation of public comment.* This section specifies 10 requests for feedback on the topics listed previously. We received feedback on these topics and provide a summary of and response to some of the comments below. We also note our intention for an additional RFI or rulemaking on this topic in the future.

1. Background

Significant and persistent inequities in health care outcomes exist in the United States. Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level, is often associated with worse health outcomes.[813] [814] [815] [816] [817] [818] [819] [820] Such disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute

[813] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011; 305(7):675–681.

[814] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013; 346.

[815] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[816] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[817] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200–8536/rural-communities-age-income-health-status-recap.pdf.*

[818] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[819] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[820] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[821] [822] [823] [824] [825] [826] Readmission rates for common conditions in the Hospital Readmissions Reduction Program are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[827] [828] [829] [830] [831] Studies have also shown that African Americans are significantly more likely than White Americans to die prematurely from heart disease and stroke.[832] The COVID–19 pandemic has further illustrated many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to White persons.[833] [834] As noted by the Centers for Disease Control ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.'' [835] One important strategy for addressing these important inequities is improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[836] For the purposes of this rule, we are using a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [837] We note that this definition was recently established and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN–QIOs); Federal, State, territorial, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[838] The CMS Equity Plan for Improving Quality in Medicare focuses on three core priority areas which inform our policies and programs: (1) Increasing understanding and awareness of health disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.[839] The CMS Quality Strategy [840] and Meaningful Measures Framework [841] also include elimination of racial and ethnic disparities as central principles. Our efforts aimed at closing the health equity gap to date have included providing transparency of health disparities, supporting providers and health officials with evidence-informed solutions to address social determinants of health and achieve health equity, and reporting to providers on gaps in quality as follows:

- The *CMS Mapping Medicare Disparities Tool* which is an interactive map that identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.[842]
- The *Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage Stratified Report,* which highlights racial and ethnic differences in health care experiences and clinical

[821] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[822] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[823] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec; 73(12):2107–15.

[824] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[825] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[826] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[827] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[828] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014. Available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/downloads/medicare-hospital-quality-chartbook-2014.pdf.*

[829] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[830] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[831] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[832] Health and Human Services. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[833] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[834] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[835] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[836] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[837] *https://www.federalregister.gov/documents/2021/01/25/2021–01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government.*

[838] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[839] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[840] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[841] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[842] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

care, compares quality of care for women and men, and looks at racial and ethnic differences in quality of care among women and men separately for Medicare Advantage plans.[843]

- The *Rural-Urban Disparities in Health Care in Medicare Report* which details rural-urban differences in health care experiences and clinical care.[844]
- The *Standardized Patient Assessment Data Elements* for certain post-acute care Quality Reporting Programs, which now includes data reporting for race and ethnicity and preferred language, in addition to screening questions for social needs (84 FR 42536 through 42588).
- *The CMS Innovation Center's Accountable Health Communities Model* which includes standardized collection of health-related social needs data.
- *The Guide to Reducing Disparities* which provides an overview of key issues related to disparities in readmissions and reviews set of activities that can help hospital leaders reduce readmissions in diverse populations.[845]
- The CMS State Health Official Letter, *Opportunities in Medicaid and CHIP to Address Social Determinants of Health (SDOH) released on January 7, 2021,* which outlines opportunities under Medicaid and the Children's Health Insurance program (CHIP) to better address SDOH and to support states with designing programs, benefits, and services that can more effectively improve population health, reduce disability, and lower overall health care costs in the Medicaid and CHIP programs by addressing SDOH.[846]
- *The CMS Disparity Methods* which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmissions Reduction Program (see 84 FR 42496 through 42500 for a discussion of using stratified data in additional measures).

These programs are informed by reports by the National Academies of Science, Engineering and Medicine (NASEM)[847] and the Office of the Assistant Secretary for Planning and Evaluation (ASPE)[848] which have examined the influence of social risk factors on several of our quality programs. In this RFI, we address only the eighth initiative as previously listed, the CMS Disparity Methods. We discuss the implementation of these methods to date and present considerations for continuing to improve and expand use of these methods to provide providers and ultimately consumers with actionable information on disparities in health care quality to support efforts at closing the equity gap.

2. Current CMS Disparity Methods

We first sought public comment on potential public reporting of hospital quality measure data stratified by social risk factors in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25199). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409), we considered potential confidential reporting of the Hospital Inpatient Quality Reporting (IQR) Program Pneumonia Readmission (NQF#0506) and Pneumonia Mortality (NQF#0468) measures stratified by dual-eligibility status. We initially focused on stratification by dual eligibility which is consistent with recommendations from ASPE's First Report to Congress which was required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185).[849] This report found that in the context of value-based purchasing (VBP) programs, dual eligibility, as an indicator of social risk, was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested. We also solicited feedback on the two potential methods for illuminating differences in outcomes rates among patient groups within a provider's patient population that would allow for a comparison of those differences, or disparities, across providers. A first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of the magnitude of disparity across hospitals, so hospitals can assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) is complementary and assesses hospitals' outcome rates for dual-eligible patients only, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. We also specifically solicited feedback on which social risk factors provide the most valuable information to stakeholders. Overall, comments supported the use of dual eligibility as a proxy for social risk, although commenters also suggested investigation of additional social risk factors, and we continue to consider which risk factors provide the most valuable information to stakeholders.

In the FY 2019 IPPS/LTCH PPS final rule (82 FR 41597 through 41601) we finalized plans to provide confidential hospital-specific reports (HSRs) containing stratified results of the Pneumonia Readmission (NQF# 0506) and Pneumonia Mortality (NQF#0468) measures including both the Across-Hospital Disparity Method and the Within-Hospital Disparity Methods (disparity methods) stratified by full-benefit dual eligibility. In the FY 2019 final rule (83 FR 41554 through 41556) we also removed six condition/procedure-specific readmission measures, including the Pneumonia Readmission Measure (NQF#0506) (83 FR 41544 through 41556) and five mortality measures, including the Pneumonia Mortality measures (NQF#0468) (83 FR 41556 through 41558) from the Hospital IQR Program. The Pneumonia Readmission measure (NQF#0506) and the other condition/procedure-specific readmission measures remained in the HRRP. We also noted in the FY 2019 final rule, that for the future, we were considering: (1) Expanding our efforts to provide stratified data in confidential HSRs for other measures; (2) including other social risk factors beyond dual eligible status in confidential HSRs; and (3) eventually, making stratified data publicly available on the *Hospital Compare* (now *Care Compare*) website or successor website (83 FR 41598). In 2019 we provided hospitals with results of the Pneumonia Readmission measure (NQF#0506) stratified using full-benefit dual eligibility. We provided this

[843] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[844] Centers for Medicare & Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.*

[845] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[846] CMS State Health Official Letter. Opportunities in Medicaid and CHIP to Address Social Determinants of Health. January 7, 2021. Available at *https://www.medicaid.gov/Federal-policy-guidance/downloads/sho21001.pdf.*

[847] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[848] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[849] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

information in annual confidential HSRs for claims-based measures.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42388 through 42390) we invited public comment on our proposal to apply the disparity methods to additional outcome measures for confidential reporting to the five additional condition/procedure-specific readmission measures: (1) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (AMI Readmission measure); (2) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (CABG Readmission measure); (3) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891) (COPD Readmission measure); (4) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization (NQF #0330) (HF Readmission measure); and (5) Hospital-Level 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) (THA/TKA Readmission measure). Many commenters supported our proposal to continue to provide hospitals with confidential hospital-specific reports on the Pneumonia Readmission measure using the two disparity methods and to expand that effort to include the five additional condition/procedure-specific readmission measures. Commenters expressed concern with stratifying measure data based only on dual-eligibility status and recommended that we continue to consider and refine additional social risk factors for stratification in confidential HSRs and specifically consider additional factors that might affect outcomes or result in higher spending, including race, ethnicity, geographic area, sex, disability, education, and access to care. A commenter expressed concern about the reliability of race and ethnicity data if CMS should consider stratifying hospital quality data by such factors and recommended that CMS develop a proposal to improve the collection of race and ethnicity data or to promote public transparency using data that are of mixed quality, before reporting such data publicly. We replied that we focused our initial efforts on providing disparity results based on dual-eligible status because of strong evidence demonstrating worse health outcomes among dual-eligible Medicare beneficiaries, and because reliable information is readily available in our administrative claims. We also noted that we continue to explore opportunities to account for additional social risk factors in the future, including evaluating new sources of social risk factor data and how to capture such data, engaging with stakeholders, and examining the availability and feasibility of accounting for social risk factors which might influence quality outcome measures.

ASPE's Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program,[850] required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, released in March 2020, recommended among other things, that CMS should explore ways to encourage providers to collect social risk information, that quality reporting programs should include health equity measures, and that quality and resource use measures should be reported separately for dually enrolled beneficiaries and other beneficiaries.

In 2020, we provided hospitals with results of each of the six condition/procedure-specific readmission measures, for which reporting requirements were met, stratified using full-benefit dual eligibility. We provided this information in annual confidential HSRs for claims-based measures. Results were made available for hospitals to download through the secure portal within the QualityNet website each spring. Results for the 2020 confidential reporting period for the CMS Disparity Methods showed worse outcomes for dually eligible beneficiaries across the majority of hospitals for all six condition-specific measures.[851] These results underscore the importance of continuing to make health care equity information more available to providers to promote quality improvement.

For additional information on the two disparity methods, we refer readers to the technical report available on the Quality Net website (*https://qualitynet.cms.gov/inpatient/measures/disparity-methods/resources#tab2*), as well as the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407).

3. Potential Expansion of the CMS Disparity Methods

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[852] As we described previously, we have been considering, among other things, expanding our efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. We sought public comment on three potential future expansions of the CMS Disparity Methods, including: (1) Future potential stratification of quality measure results by race and ethnicity, (2) improving demographic data collection; and (3) the potential creation of a *Hospital Equity Score* to synthesize results across multiple social risk factors.

a. Future Potential Stratification of Quality Measure Results by Race and Ethnicity

The Administration's *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* directs agencies to assess potential barriers that underserved communities and individuals may face to enrollment in and access to benefits and services in Federal Programs. As summarized previously, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and procedural complications. We are considering expanding the disparity methods to include stratification of the condition/procedure-specific readmission measures by race and ethnicity. The 1997 Office of Management and Budget (OMB) Revisions to the Standards for the Collection of Federal Data on Race and Ethnicity, outlines the racial and ethnic categories which may potentially be used for reporting the disparity methods, which we note are intended to be considered as social and cultural, and not biological or genetic.[853] The

[850] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[851] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

[852] Centers for Medicare Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[853] Revisions to the standards for the classification of Federal data on race and ethnicity. 62 FR 58782–58790.

1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. In the OMB standards, Hispanic or Latino is the only ethnicity category included, and since race and ethnicity are two separate and distinct concepts, persons who report themselves as Hispanic or Latino can be of any race.[854] Another example, the ''Race & Ethnicity—CDC'' code system in PHIN Vocabulary Access and Distribution System (VADS) [855] permits a more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity. Further, the ''Race & Ethnicity—CDC'' code system has a hierarchy that rolls up to the OMB minimum categories for race and ethnicity and, thus, supports aggregation and reporting using the OMB standard. ONC includes both the CDC and OMB standards in its criterion for certified health IT products.[856] For race and ethnicity, a certified health IT product must be able to express both detailed races and ethnicities using *any* of the 900 plus concepts in the ''Race & Ethnicity—CDC'' code system in the Public Health Information Network (PHIN) Vocabulary Access and Distribution Systems (VADS), as well as aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity. This approach can reduce burden on providers recording demographics using certified products.

Self-reported race and ethnicity data are the gold standard for classifying an individual according to race or ethnicity. However, CMS currently does not consistently collect self-reported race and ethnicity for the Medicare program, but instead gets the data from the Social Security Administration (SSA) and the data accuracy and comprehensiveness have proven challenging despite capabilities in the marketplace via certified health IT products. Historical inaccuracies in Federal data systems and limited collection classifications have also contributed to the limited quality of race and ethnicity information in our administrative data systems.[857] In recent decades, to address these data quality issues, we have undertaken numerous initiatives, including updating data taxonomies and conducting direct mailings to some beneficiaries to enable more comprehensive racial and ethnic identification.[858] [859] Despite those efforts, studies reveal varying data accuracy in identification of racial and ethnic groups in Medicare administrative data, with higher sensitivity for correctly identifying White and Black individuals, and lower sensitivity for correctly identifying individuals of Hispanic ethnicity or of Asian/Pacific Islander (API) and American Indian/Alaskan Native race.[860] Incorrectly classified race or ethnicity may result in overestimation or underestimation in the quality of care received by certain groups of beneficiaries.

We continue to work with Federal and private partners to better collect and leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection [861] and supported collection of specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health, and sponsored several initiatives to statistically estimate race and ethnicity information when it is absent.[862] The Office of the National Coordinator for Health Information Technology (ONC) included social, psychological, and behavioral standards in the 2015 Edition health information technology certification criteria (2015 Edition), providing interoperability standards (LOINC [Logical Observation Identifiers Names and Codes] and SNOMED CT [Systematized Nomenclature of Medicine—Clinical Terms]) for financial strain, education, social connection and isolation, and others. Additional stakeholder efforts underway to expand capabilities to capture additional social determinants of health data elements include the Gravity Project to identify and harmonize social risk factor data for interoperable electronic health information exchange for EHR fields, as well as proposals to expand the ICD–10 (International Classification of Diseases, Tenth Revision) Z-codes, the alphanumeric codes used worldwide to represent diagnoses.[863]

While development of sustainable and consistent programs to collect data on social determinants of health can be considerable undertakings, we recognize that another method to identify better race and ethnicity data is needed in the short term to address the need for reporting on health equity. In working with our contractors, two algorithms have been developed to *indirectly estimate* the race and ethnicity of Medicare beneficiaries (as described further in the next section). We believe that using indirect estimation can help to overcome the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirect estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on hospitals as these data are derived using existing administrative and census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[864] Indirectly estimated data

[854] *https://www.census.gov/topics/population/hispanic-origin/about.html.*

[855] *https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520.*

[856] See *https://www.healthit.gov/isa/representing-patient-race-and-ethnicity.* For more information about the certification criterion for ''Demographics'' in the ONC Health IT Certification program, see *https://www.healthit.gov/test-method/demographics.*

[857] Zaslavasky AM, Ayanian JZ, Zaborski LB. The validity of racial and ethnic codes in enrollment data for Medicare beneficiaries. Health Services Research, 2012 Jun (47) (3 Pt 2): 1300–21.

[858] Filice CE, Joynt KE. Examining Race and Ethnicity Information in Medicare Administrative Data. Med Care. 2017; 55(12):e170-e176. doi:10.1097/MLR.0000000000000608.

[859] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[860] Zaslavsky AM, Ayanian JZ, Zaborski LB. The validity of race and ethnicity in enrollment data for Medicare beneficiaries. Health Serv Res. 2012 Jun;47(3 Pt 2):1300–21.

[861] Centers for Medicare & Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[862] *https://pubmed.ncbi.nlm.nih.gov/18567241/*,*https://pubmed.ncbi.nlm.nih.gov/30506674/*, Eicheldinger C, Bonito A. More accurate racial and ethnic codes for Medicare administrative data. *Health Care Financ Rev.* 2008; 29(3):27–42. Haas A, Elliott MN, Dembosky JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res.* 2019; 54(1):13–23. doi:10.1111/1475–6773.13099.

[863] *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[864] Institute of Medicine. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The

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are most commonly used at the population level (such as the hospital or health plan-level) where aggregated results form a more accurate description of the population than existing, imperfect data sets. These methods often estimate race and ethnicity using a combination of other data sources which are predictive of self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[865]

As described earlier, we previously supported the development of two such methods of indirect estimation of race and ethnicity among Medicare beneficiaries. One indirect estimation approach developed by our contractor uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, State of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or Asian/Pacific Islander (API).[866] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups.[867]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C & D performance data for Medicare Advantage Plans by race and ethnicity.[868] Validation testing reveals concordances of 0.88 through 0.95 between indirectly estimated and self report among individuals who identify as White, Black, Hispanic, and API for MBISG version 2.0 and concordances with self-reported race and ethnicity of 0.96 through 0.99 for these API, Black, Hispanic, and White beneficiaries for MBISG version 2.1.[869] [870] [871] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial. [872] Indirect estimation can be a statistically reliable approach for calculating population-level equity results for groups of individuals (such as the hospital-level) and is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual.

However, despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration, there remains the small risk of unintentionally introducing measurement bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We believe this amount of bias is considerably less than would be expected if stratified reporting were conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for improving demographic data collection to progress. We were interested in learning more about, and solicited comments about, the potential benefits and challenges associated with measuring hospital equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

b. Improving Demographic Data Collection

Stratified hospital-level reporting using indirectly estimated race and ethnicity would represent an important advance in our ability to provide accurate equity reports to hospitals. However, self-reported race and ethnicity data are the gold standard for classifying an individual according to race or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[873] Collection and sharing of a standardized set of social, psychological, and behavioral data by hospitals, including race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[874] This could

National Academies Press. Available at: *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

[865] Institute of Medicine. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press. Available at: *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

[866] Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008. Available at: *https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.233.6403&rep=rep1&type=pdf.*

[867] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research,* 54:13–23 and Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6338295/pdf/HESR-54-13.pdf.*

[868] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[869] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[870] MBISG 2.1 validation results performed under contract #GS–10F–0012Y/HHSM–500–2016–00097G. Pending public release of the 2021 Part C and D Performance Data Stratified by Race, Ethnicity, and Gender Report, available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[871] We note to readers that in this final rule we clarify this sentence to read as follows: Validation testing reveals concordances with self-reported race and ethnicity of 0.96 through 0.99 for API, Black, Hispanic, and White beneficiaries for MBISG version 2.1.59.

[872] Haas, A, Elliott, MN, Dembosky, JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13–23. *https://doi.org/10.1111/1475-6773.13099.*

[873] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[874] The Office of the National Coordinator for Health Information Technology. United State Core

potentially include expansion of stratified reporting to additional social factors, such as language preference and disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering all demographic questions, and that individual preferences for non-response are maintained.

We note that eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program must use certified EHR technology (CEHRT) that has been certified to the 2015 Edition of health IT certification criteria. As noted previously, the certification criterion for Demographics under the 2015 Edition (at 45 CFR 170.315(a)(5)) supports collection of data using both the OMB standards for collecting data on race and ethnicity as well as the more granular ''Race & Ethnicity—CDC'' standard. In the 2020 ONC 21st Century Cures Act final rule, ONC also adopted a new framework for the core data set which certified health IT products must exchange, called the United States Core Data for Interoperability (USCDI) (85 FR 25669). The USCDI incorporates the demographic data and associated code sets finalized for the 2015 Edition certification criteria.

As noted previously, ONC also finalized a certification criterion in the 2015 Edition which supports a certified health IT product's ability to collect social, psychological, and behavioral data (at 45 CFR 170.315(a)(15)). However, this functionality is not included as part of the certified EHR technology required by the Promoting Interoperability program. While the technical functionality exists to achieve the gold standard of data collection, we understand challenges and barriers exist in using the technologies with these capabilities.

We were interested in learning about, and solicited comments on, current data collection practices by hospitals to capture demographic data elements (such as race, ethnicity, sex, sexual orientation, and gender identity (SOGI), language preference, tribal membership, and disability status). Further, we sought comment on potential challenges facing hospital collection, at the time of admission, of a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act [875]) and standards for interoperable exchange (such as the United States Core Data for Interoperability incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria [876]). Advancing data interoperability through collection of a minimum set of demographic data collection, and incorporation of this demographic information into quality measure specifications, has the potential for improving the robustness of the disparity method results, potentially permitting reporting using more accurate, self-reported information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

c. Potential Creation of a Hospital Equity Score To Synthesize Results Across Multiple Social Risk Factors

As we previously described, we are considering expanding the disparity methods to include two social risk factors (dual eligibility which is currently reported and race/ethnicity, which is considered here in this RFI). This approach would improve the comprehensiveness of health equity information provided to hospitals. Aggregated results from multiple measures and multiple social factors, using output from the disparity methods, in the format of a summary score, can improve the usefulness of the equity results. In working with our contractors, we recently developed an equity summary score for Medicare Advantage contracts/plans, the Health Equity Summary Score (HESS), with application to stratified reporting using two social risk factors: Dual eligibility and race and ethnicity, as described in *Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score.*[877]

The HESS calculates standardized and combined performance scores synthesized across the two social risk factors. The HESS also combines results of the within-plan method (similar to the Within-Hospital method) and across-plan method (similar to the Across-Hospital method) across multiple performance measures.[878]

We are considering creating a *Hospital Equity Score,* not yet developed, which would be modeled off the HESS, but adapted to the context of risk-adjusted hospital outcome measures and potentially other hospital quality measures used in CMS programs. We envision that the *Hospital Equity Score* would synthesize results for a range of measures and use multiple social risk factors which have been reported to hospitals as part of the CMS Disparity Methods. We believe that creation of the *Hospital Equity Score* has the potential to supplement the overall measure data already reporting on the *Care Compare* or successor website, by providing easy to interpret information regarding disparities measured within individual hospitals and across hospitals nationally. A summary score would be useful to decrease burden by minimizing the number of measure results provided and providing an overall indicator of equity.

The *Hospital Equity Score* under consideration would potentially—

- Summarize hospital performance across multiple social risk factors (initially dual eligibility and race and ethnicity, as described previously); and
- Summarize hospital performance across the two disparity methods (that is, the Within-Hospital Disparity Method and the Across-Hospital Disparity Method) and potentially multiple measures.

Prior to any potential future public reporting, if we determine that a *Hospital Equity Score* can be feasibly and accurately calculated, we intend to initially provide results of the *Hospital Equity Score* in confidential HSRs which hospitals will be able download. Any potential future proposal to display the *Hospital Equity Score* on the *Care Compare* or successor website would be made through future rulemaking.

4. Solicitation of Public Comment

We sought comment on the possibility of expanding our current disparities methods to include reporting by race and ethnicity using indirect estimation. We also sought comment on the possibility of hospital collection of standardized demographic information for the purposes of potentially incorporating into measure specifications to permit more robust equity measurement. Additionally, we sought comment on the design of a

Data for Interoperability Draft Version 2. 2021. Available at: *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.*

[875] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[876] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[877] Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score. J Gen Intern Med. Published online November 11, 2019. doi:10.1007/s11606–019–05473–x.

[878] Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score. J Gen Intern Med. Published online November 11, 2019. doi:10.1007/s11606–019–05473–x.

Hospital Equity Score for calculating results across multiple social risk factors and measures, including race/ethnicity and dual eligibility. Any data pertaining to these areas that are recommended for collection for measure reporting for a CMS program and any potential public disclosure on *Care Compare* or successor website would be addressed through separate and future notice- and-comment rulemaking. We plan to continue working with ASPE, hospitals, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all patients and minimizing unintended consequences. We received feedback on these topics and provide a summary of and response to some of the comments below. We also note our intention for additional RFI or rulemaking on this topic in the future.

Specifically, we invited public comment on the following:

• Future Potential Stratification of Quality Measure Results by Race and Ethnicity

++ The potential future application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures (in addition to dual-eligibility) for hospital—level disparity reporting, until more accurate forms of self-identified demographic information are available.

++ Appropriate privacy safeguards with respect to data produced from the indirect estimation of race and ethnicity to ensure that such data is properly identified if/when it is shared with providers.

++ Ways to address the challenges of defining and collecting accurate and standardized self-identified demographic information, including information on race and ethnicity, disability, and language preference for the purposes of reporting, measure stratification, and other data collection efforts relating to quality.

++ Recommendations for other types of feasibly collected data elements for measuring disadvantage and discrimination, for the purposes of quality reporting and measure stratification, in addition to, or in combination with, race and ethnicity.

++ Recommendations for other types of quality measures or measurement domains, in addition to readmission measures, to prioritize for stratified reporting by dual eligibility, race and ethnicity, and disability.

++ Examples of approaches, methods, research, and/or considerations for use of data-driven technologies that do not facilitate exacerbation of health inequities, recognizing that biases may occur in algorithms or be encoded in datasets.

• Improving Demographic Data Collection

++ Experiences of users of certified health IT regarding local adoption of practices for collection of demographic elements, the perceived value of using these data for improving decision-making and care delivery, and the potential challenges and benefits of collecting and using more granular, structured demographic information, such as the ''Race & Ethnicity—CDC'' code system.

++ The possible collection of a minimum set of demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, tribal membership, and disability status), by hospitals at the time of admission, using electronic data definitions which permit nationwide, interoperable health information exchange, for the purposes of incorporating into measure specifications and other data collection efforts relating to quality.

• Potential Creation of a Hospital Equity Score To Synthesize Results Across Multiple Social Risk Factors

++ The possible creation and confidential reporting of a *Hospital Equity Score* to synthesize results across multiple social risk factors, proxies for social risk, and disparity measures.

++ Interventions hospitals could institute to improve a low *Hospital Equity Score* and how improved demographic data could assist with these efforts.

We received comments on these topics.

Comment: Many commenters supported the collection of data that would permit stratification of quality measures by race, ethnicity, and dual eligibility status. Some commenters recommended that CMS continue to explore ways to stratify quality measures, such as including more subcategories for race and ethnicity or collecting data on additional demographic categories like language and disability. A commenter noted that CMS could provide confidential feedback reports regarding quality measures stratified using such data. Several commenters noted that such stratified reporting could lead to more targeted interventions. A commenter was concerned about reporting stratified measures, noting that some categories for race and ethnicity may have small sample sizes. Another commenter was concerned that expanding stratified reporting may increase burden on providers and negatively impact the patient experience.

Response: We thank the commenters for their feedback. We agree that stratified hospital-level reporting by dual eligibility status, indirectly estimated race and ethnicity, and other demographic and social factors has potential to support quality improvement activities to improve quality of care and reduce disparities in hospital outcomes. We intend to provide future confidential feedback reports to providers on quality measure performance across our quality programs, broken out by race and ethnicity. We will consider the feasibility of measures for stratification and specific programs for confidential reporting, as well as the timeframes for confidential reporting and a potential transition to public reporting on an individual basis in collaboration with our stakeholders.

Comment: Commenters also noted the need to create standards for data collection, as these standards could impact stratification. A commenter noted that the demand on provider staff resources should be considered as CMS develops standards and methodologies for collecting demographic data. Methodologies for stratification could include ways to compare similar facilities characterized by payer mix, patient mix, and levels of funding and resources. A commenter noted that lack of standardization in data collection could impact documentation of mixed-race individuals specifically.

Response: We appreciate the feedback provided by the commenters regarding approaches for incorporating additional demographic characteristics into analyses that address and advance health equity. When considering future policy development, CMS intends that conduct any future collection of demographic and social risk factor data would be conducted in a manner that minimizes provider reporting burden. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters supported the indirect estimation of race and ethnicity but noted some caveats. For example, commenters recommended that methods for indirect estimation should be validated and vetted by recognized authorities such as the National Quality Forum. A commenter noted that indirect estimation of race and ethnicity could help overcome limitations regarding demographic information available in existing data sources. Several commenters preferred using self-

reported data to identify race and ethnicity, rather than indirect methods, noting that self-reported data is the preferred ''gold-standard'' for information on these demographic characteristics. A commenter suggested that indirect estimation should be used to assist hospitals in assessing race and ethnicity data completeness, rather than using outcome performance. A few commenters opposed indirect estimation because it may introduce bias in data or discourage hospitals from improving their data collection efforts. These commenters recommended CMS focus on supporting efforts to improve data collection instead of indirect estimation. For example, a commenter recommended training providers to get better self-reported data from individuals. A commenter provided feedback about the methodology for indirect estimation and noted that using first and last names matched to specific national origin groups, and using the racial and ethnic composition of the neighborhood surrounding a particular facility is not recommended because it too closely resembles a long standing 'racial profiling' stigma.

Response: We are sensitive to the concerns raised by stakeholders about indirect estimation. As we summarized in the FY 2022 IPPS/LTCH PPS proposed rule, the Medicare program has historically not collected information directly from beneficiaries on race and ethnicity, instead relying on data collected by the Social Security Administration, which is limited in several ways. A number of barriers contribute to this information being insufficiently accurate to examine hospital-level disparities (86 FR 25558 through 25561). For example, prior to 1980, only three categories (White, Black, and Other) were available for individuals to self-report race, and respondents were not able to indicate Asian, American Indian/Alaska Native, Hispanic, or Pacific Islander identities. As a result of these constrained response options, many current beneficiaries may not have had the opportunity to accurately self-report their race and ethnicity. Although we have undertaken significant efforts to update incorrect race and ethnicity information many inaccuracies remain, limiting our ability to accurately measure disparities. In addition, there is a significant portion of beneficiaries for which race and ethnicity has not been collected and is unknown.

As summarized in the FY 2022 IPPS/LTCH PPS proposed rule, in recent years we have sponsored the development of two indirect estimation algorithms, both intended to correct and improve administrative information on race and ethnicity (86 FR 25558 through 25561). Indirect estimation methods such as these can generally be used in two different ways (a) to estimate race and ethnicity in the absence of self-reported data or to (b) improve administrative data in which beneficiaries provided a self-report of race and ethnicity but were not permitted a full set of response options (post-1980).[879] While there is evidence supporting the validity of both approaches, the method described in (b) has proven to be particularly accurate, where indirect estimation allows better estimation of the responses people would give when permitted a full set of response options, based on the administrative variables. The option we are considering, as described situation (b) uses an algorithm to augment existing data to allow a constrained administrative self-reported variable to better match what Medicare beneficiaries themselves may have chosen when given a comprehensive set of response options on race and ethnicity.

One of the algorithms under consideration, the Medicare Bayesian Improved Surname Geocoding Version 2.1 (MBISG) uses the original beneficiary self-report, but uses additional information supplied by Medicare beneficiaries and information about neighborhood composition, to provide a better estimation of what Medicare beneficiaries would self-report when given a full set of response options for race and ethnicity. With respect to Asian and Pacific Islander, Black, Hispanic and White Medicare beneficiaries, the improved version of the administrative variable has 96–99 percent concordance with what Medicare beneficiaries themselves report when allowed a full set of response options, matching better than the original self-reported variable in which most Medicare beneficiaries were not allowed to indicate Asian, American Indian/Alaska Native, Hispanic, or Pacific Islander identities.[880] The MBISG also offers distinct advantages because it generates probabilities of identification in each racial and ethnic group for each beneficiary, as opposed to an assignment to a single group, allowing for more robust disparity estimates that reflect individuals who identify with more than one racial or ethnic group.

The MBISG incorporates multiple sources of information to develop probabilities for beneficiary identification with particular racial and ethnic groups. In addition to surname matching, where accuracy may vary within certain national origin groups, the model also considers information on race and ethnicity which that person reported to the SSA, the person's first name, the composition of the census block group where they live, and other demographic information that Medicare beneficiary shared. Through such a holistic approach, the MBISG can make accurate comparisons between groups of Medicare beneficiaries regarding the quality of care received, including groups where surname matching alone may be less accurate, for example, people of certain national origin groups and people who changed their surnames upon marriage. The MBISG is also designed to consider those who identify as multiracial and allows measurement in Census categories that distinguish those who chose a single racial identity or more than one, as well as considering endorsement of Hispanic ethnicity. Notably, we do not believe the MBISG is well suited to make inferences about single individuals, only inferences about aggregated groups; while individuals may be misclassified based on names or residence, validation studies indicate that in aggregate these errors do not bias the results in either direction.

We agree that self-reported demographic information is the gold standard and are committed to continuing to efforts to enhance data collection, standardization, and interoperability, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule, although we recognize that these efforts often take time to materialize (86 FR 25554 through 25561). We believe that use of statistical imputation models, such as the MBISG, will permit us to provide more accurate, less biased information on disparities in hospital outcomes until higher quality data are available. As noted in IX.B.3 we intend to provide information to providers on quality measure performance across our quality programs in the future, broken out by race and ethnicity in confidential feedback reports. We will consider the timeframe for confidential and public reporting, measures to include in reporting, methodological feasibility, and specific programs, on an individual

[879] Office of Management and Budget, DIRECTIVE NO. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting, available at: *https://wonder.cdc.gov/wonder/help/populations/bridged-race/directive15.html.*

[880] MBISG 2.1 validation results performed under contract #GS–10F–0012Y/HHSM–500–2016–00097G. Pending public release of the 2021 Part C and D Performance Data Stratified by Race, Ethnicity, and Gender Report, available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

basis in collaboration with our stakeholders.

Comment: Many commenters supported the collection of additional social and demographic data, including the development of a minimum dataset. A commenter noted using the ONC United States Core Data for Interoperability as a minimum dataset would be one method of ensuring standardization and accuracy in reported data. Commenters agreed that a standardized approach for data collection is necessary to have complete and consistent data and would lead to more accurate stratification of quality measures. Some commenters recommended that data collection approaches should align with requirements for other state or Federal agencies and programs. For example, a commenter suggested working with the OMB to refine and update the Federal requirements for social determinants of health and sexual orientation and gender identity data collection. A commenter suggested that a standardized data collection system was necessary to create a health equity score and explore disparities. Some commenters suggested that standards should include precautions for privacy and security to protect data. A few commenters suggested using incentives to improve data collection efforts, including financial incentives.

Response: We appreciate all of the comments and interest regarding the collection and standardization of social/demographic data. We will take commenters' feedback into consideration in future policy development.

Comment: Commenters recommended a variety of additional social and demographic data that they believe should be collected. Examples of additional information that could be collected from individuals include gender expression, LGBTQ+ status, disability status, language including English proficiency, zip code, housing security, food security, transportation needs, safety, veteran status, health literacy, functional, and cognitive status along with a person's activities of daily living and independent activities of daily living, ability to communicate, insurance coverage, access to technology, forms of economic or financial insecurity, availability of caregiver support, tribal membership, body mass index (BMI), smoking status, back pain, pain in extremities, and health risk status based on existing indexes of risk (such as the Charlson Comorbidity Index). A commenter recommended evaluating all inpatient and outpatient codes for depression mental health status, chronic narcotic or pre-operative narcotic use. A commenter cautioned that asking patients about immigration status may discourage patients from obtaining care. Another commenter suggested considering a structural measure of disparities such as how the physical and technological infrastructure available in communities supports delivery of care.

Response: We appreciate the feedback provided by the commenters regarding approaches for incorporating other demographic characteristics into analyses that address and advance health equity. We will take commenters' feedback into consideration in future policy development.

Comment: Many commenters expressed concern that additional data collection efforts may place an undue burden on providers and administrators, and would impose an additional financial burden. Some commenters opposed creating a ''mandate'' for additional data collection. Commenters recommended providing additional resources to support data collection, data analysis, and quality improvement activities, such as, provider and staff training and education, and education for the public. Certain commenters suggested alternatives to reduce provider burden. For example, some commenters discussed using existing data sources (for example, the HIPAA transaction dataset for social risk factor fields) to build a health equity framework. Another commenter suggested delaying the collection of additional social and demographic information until 2024 since hospitals are trying to comply with other CMS reporting and interoperability requirements. Other commenters suggested making targeted changes to Medicare programs to reduce the perceived burden.

Response: We appreciate the feedback provided by the commenters. We are sensitive to the potential for increased administrative burden associated with improved data collection practices. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters recommended engaging with stakeholders to improve data collection efforts and develop standards for data collection. Commenters suggested working with both patients and providers to refine the data collection process, develop clear and clinically meaningful reasons and rationales regarding why it is important to collect these data elements, and demonstrate how these elements support a patient-centered healthcare delivery approach. A commenter suggested creating a public-private partnership to improve data collection and take action based on disparity data. Commenters had several suggestions for improving the data collection process; for example, several commenters noted that questions for collection of additional demographic information should be consistent with the 2020 Census. Another commenter suggested including demographic elements from the HL7 Gravity Project.

Response: We appreciate the feedback provided by the commenters regarding ways to engage with stakeholders to improve demographic and social risk factor data collection. We will take commenters' feedback into consideration in future policy development.

Comment: A commenter noted that upgrades to EHRs and related billing systems would be needed to standardize data collection processes. Several commenters discussed using electronic medical records to collect demographic information but expressed concerns about data standardization. A commenter suggested that CMS consider using a patient API tool as a means of collecting self-reported patient data. A commenter recommended including additional ICD–10 codes on claims and coordinating with the National Uniform Billing Committee (NUBC) on the utilization of the existing 'patient reason for visit' fields that are currently available on institutional claims in order to collect additional social and demographic information. Several commenters suggested using HIEs to enhance and close the gaps in demographic data in the electronic health record because they can serve as a central hub for information sharing and confirm uniform requirements for data fields.

Response: We appreciate the feedback and suggestions provided by the commenters regarding ways to improve demographic and social risk factor data collection. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters noted that providers would need to train their staff to ensure accurate data collection, including on the definitions of data elements and the language used to describe data categories. Commenters noted that data collection processes would need to be culturally sensitive. A commenter suggested that improvement in self-reporting would require providers to build trust through education, transparency, accountability, and the incorporation of health equity into health outcome measures. Another commenter described how patient

hesitation or other barriers could impact the data collection process, for example based on the fact that this data collection is voluntary for patients and not always completed. A commenter recommended that data collection efforts should accommodate various literacy levels and the linguistic needs of patient populations. A few commenters discussed the timing of the collection of data and recommended including data collection processes at the front end of the health care visit, such as at the time of hospital admission, as well as at the time of Medicare enrollment. A commenter questioned whether point-of-admission would be the most efficient patient-focused way of collecting this information and recommended using a patient portal instead, where patients may provide or update their information at any time.

Response: We appreciate the feedback provided by the commenters regarding ways to engage with stakeholders to improve data collection on demographic and social risk factors, and ways to improve data collection through culturally sensitive methods. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters recommended additional measures, either new or existing, that they believe should be considered for stratified reporting, such as measurement of care coordination and partnership with ambulatory and community organizations. Commenters suggested that selected measures should be clinically relevant and patient-centric. A commenter suggested considering measures that group clinical and social risk together to better identify high risk patients, facilitate care management, and allow for management of a greater number of risk factors. Commenters recommended that measures should not be adopted and publicly reported until they are validated, standardized data is available across all provider settings, and the potential for improvement by using these measures is demonstrated. Commenters agreed, however, that these results could be useful for internal purposes as indicators of potential disparity at facilities. A commenter suggested that people should be grouped into similar clinical risk groups when identifying equity in care delivery.

Response: We appreciate the feedback provided by the commenters regarding approaches for incorporating additional social and demographic factors into analyses that address and advance health equity, and about the use of these results. We also note for stakeholders that The Office of the National Coordinator (ONC) for Health Information Technology recently issued ONC Standards Bulletin 2021–2 (SB21–2) which describes the specific capabilities health IT certified through the ONC Health IT Certification Program must have with respect to capturing and exchanging granular patient race and ethnicity data.[881] We will take commenters' feedback into consideration in future policy development.

Comment: Commenters suggested several strategies to create, validate, and test measures including consulting the National Quality Forum and working with other stakeholder groups. A commenter suggested modifying patient satisfaction surveys to collect additional information about patients' lived experiences. Another commenter encouraged the development of measures that create transparent, available, and meaningful data sets, including patient survival, function, and experience of care.

Response: We appreciate the feedback provided by the commenters regarding strategies to create, validate, and test additional measures of equity. We will continue to take these suggestions into account in future policy development.

Comment: Many commenters suggested CMS consider a variety of measures that could be included for stratification. Some measures addressed aspects of the care process such as coordination, access to health care, care transitions, readmission, or patient experience of care. A commenter suggested that measures relating to the care process could be stratified by payer type. Some of these measures were specific to the setting, such as long-term care hospitals or the emergency department. Other measures were disease or condition specific such cardiovascular disease, diabetes, cancer, surgery, and opioid and drug abuse. A few commenters suggested stratifying disease-specific mortality measures and measures related to infection control and prevention. Some commenters suggested including measures to assess the value of care by examining the Medicare spending per beneficiary. A commenter suggested exploring measures to assess the potential impact of the built environment or neighborhood.

Response: We appreciate the feedback provided by the commenters regarding additional measures that could be considered for future stratification. We will take commenters' feedback into consideration in future policy development.

Comment: Commenters had diverse views regarding the creation of a *Hospital Equity Score.* Some commenters supported the creation of such a score, while others opposed it. Commenters had several recommendations for steps CMS could take in creating a *Hospital Equity Score* including consulting with experts and issuing an additional RFI specifically focused on the creation of a *Hospital Equity Score,* to address the necessary conceptual and technical components. Some commenters encouraged CMS to create a stakeholder group to discuss the development of such a score.

Response: We appreciate the feedback provided by the commenters regarding approaches for creating a succinct summary score for measuring health equity in the hospital setting. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters opposed the creation of a *Hospital Equity Score.* Reasons commenters cited included a potential lack of accuracy, and low confidence that a summary score would provide information that could further improvement or empower patients. A commenter suggested that combined scores may be easily misinterpreted, and it would be more helpful to provide the scores for individual data elements that make up the summary score. A commenter noted that a score could negatively affect community perception of healthcare. A few commenters requested additional information about how the *Hospital Equity Score* would be used, the types of components that would be included in the score, and if the score would be tied to a program incentive.

Response: We appreciate the feedback provided by the commenters regarding approaches for creating a succinct summary score for measuring health equity in the hospital setting. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters suggested that scores would need to be based on complete and accurate data collected from a standardized data collection process. A commenter recommended delaying implementation of a score until data are accurate, or including a ramp up period before any public reporting of these scores or before penalties are imposed. Commenters described technical and

[881] The Office of the National Coordinator for Health Information Technology, ONC Health IT Standards Bulletin May 2021, Issue 2021–2, available at: *https://www.healthit.gov/sites/default/files/page/2021-5/Standards_Bulletin_2021-2.pdf.*

methodological challenges for calculating equity scores, such as imputing missing information without biasing the score, accounting for small sample sizes, and comparing scores with and across hospitals. A commenter was concerned that the score would require a complex aggregation methodology. Another suggested identifying reliable and valid methods of analyzing data. Commenters suggested that additional datapoints may be necessary to better approximate health equity. A commenter recommended considering Human Rights Campaign Equality Health Index. Another suggested that the score could be based on subpopulations within a hospital's population where services are provided.

Response: We appreciate the feedback provided by the commenters regarding approaches for creating a succinct summary score for measuring health equity in the hospital setting. We will take commenters' feedback into consideration in future policy development.

Comment: Some commenters were concerned about providers being held accountable for factors outside of their control. Some commenters suggested minimizing penalties to hospitals who provide care for vulnerable populations. Other commenters suggested calibrating or adjusting the score for social determinants of health or using risk adjustment when comparing scores.

Response: We appreciate the feedback provided by the commenters regarding approaches for creating a succinct summary score for measuring health equity in the hospital setting. We will take commenters' feedback into consideration in future policy development.

Comment: Some commenters noted that strategies to improve low scores or minimize data quality issues related to reporting scores are needed. For example, a commenter suggested providing correction action plans to improve low scores. Some commenters discouraged providing incentives based on the score or tying the score to reimbursement, while others suggested including incentive to encourage hospitals to participate.

Response: We appreciate the feedback provided by the commenters regarding approaches for creating a succinct summary score for measuring health equity in the hospital setting. We will take commenters' feedback into consideration in future policy development.

Comment: Many commenters expressed overall support of CMS' goals to advance health equity. Some commenters expressed a belief in the need to further extend and clarify the definition of equity provided in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25555). Commenters also noted that where possible equity initiatives should utilize existing systems and aim for standardization of data collection across agencies and programs, produce actionable and rigorous data, and work to avoid increasing the administrative or financial burden on providers. Some of the existing efforts, systems, and organizations that commenters identified as potentially being useful for future efforts include ICD–10–CM codes for social risk factors, the HL7 Gravity Project, and Patient ID Now Coalition. Some commenters recommended aligning aspects of Medicare and Medicaid programs to promote health equity efforts across patient populations. Several commenters expressed a desire for more clarity surrounding the definitions of health equity terms such as ''social risk factors'' to reduce ambiguity of measure construction. Multiple commenters asked CMS to consider the limitations on using claims data for health equity with regards to cancer patients. A commenter noted that claims data cannot capture the full scope of relevant clinical risk, including cancer stage, genetic and genomic data, prior treatments, disease-specific risk scoring, or other key data essential for the high-complexity decision-making required to deliver excellent and transformative cancer care. Some commenters expressed a desire to publicize health equity data in order to showcase efforts to address inequities in the healthcare space to the broader community, while others suggested that health equity data should be reported confidentially until providers understand and are able to effectively use these measures. Finally, multiple commenters recommended that CMS focus on interventions for health equity that would yield immediate benefits for patients.

Response: We appreciate the feedback provided by the commenters regarding measuring health equity in our hospital quality measurement programs. We will take commenters' feedback into consideration in future policy development.

C. Hospital Inpatient Quality Reporting (IQR) Program

1. Background and History of the Hospital IQR Program

The Hospital IQR Program strives to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians by using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across the U.S. Department of Health and Human Services (HHS), we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves.

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. The adoption of widely agreed upon quality and cost measures supports this effort. We work with relevant stakeholders to define measures in almost every care setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150);

- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509); and
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959).

We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless a different or more limited time period is finalized in the measure proposals. Measures are retained unless we propose to remove, suspend, or replace the measures. We did not propose any changes to these policies in the proposed rule.

3. Removal Factors for Hospital IQR Program Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors. We did not propose any changes to these policies in the proposed rule.

4. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Framework, our objectives under this Framework for quality measurement, and the quality topics that we have identified as high-impact measurement areas that are relevant and meaningful to both patients and providers. We did not propose any changes to these policies in the proposed rule. We also note that the Hospital IQR Program must first adopt measures and publicly report them on the *Care Compare* and/or its successor website for at least one year before the Hospital VBP Program is able to adopt them. We view the value-based purchasing programs, including the Hospital VBP Program, as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries.

5. New Measures for the Hospital IQR Program Measure Set

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25562 through 25579), we proposed to adopt five new measures: (1) Maternal Morbidity structural measure, beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination; (2) Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure beginning with a voluntary submission period which will run from July 1, 2022 through June 30, 2023, followed by mandatory reporting beginning with the reporting period which runs July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination; (3) COVID-19-Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination; (4) Hospital Harm—Severe Hypoglycemia eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination; and (5) Hospital Harm—Severe Hyperglycemia eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination. We are finalizing the adoption of these measures, and we discuss these measures in the following sections in more detail.

a. Adoption of the Maternal Morbidity Structural Measure Beginning With a Shortened Reporting Period From October 1, 2021 Through December 31, 2021, Affecting the FY 2023 Payment Determination, Followed by Annual Reporting Periods for Subsequent Years

(1) Background

Despite the highest rate of spending on maternity care, the U.S. ranks worse than most other developed nations in preventing pregnancy-related deaths.[882] The Maternal Mortality Rate in the U.S. increased from 17 deaths per 100,000 live births in 1990 to 26 deaths per 100,000 live births in 2015.[883] Similar to maternal mortality, maternal morbidity is highly preventable.[884] Without proper treatment, maternal morbidities can lead to mortality.[885] Researchers have found that the presence of select maternal morbidities such as chronic hypertension and preeclampsia were strongly associated with increased odds of mortality at the time of delivery.[886] Timely and appropriate treatment of maternal morbidities is imperative to prevent complications that can lead to maternal mortality.[887]

One of the main factors contributing to the increase in maternal morbidity and mortality is inconsistent obstetric practice.[888] Hospitals in the U.S. lack standardized protocols to address obstetric emergencies and complications that arise during pregnancy and childbirth.[889] A standardized approach to address these concerns is necessary to effectively manage obstetric emergencies and complications.[890] Thus, assessing hospital engagement in implementing standardized protocols is essential to efficiently manage maternal morbidity nationally. Addressing this maternal health crisis and improving maternal health is a priority and a quality improvement goal for CMS.

Therefore, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25562 through 25565), we proposed to adopt the Maternal Morbidity structural measure, beginning with a shortened reporting period running from October

[882] Maternal Health in the United States. Maternal Health Task Force at the Harvard Chan School. Available at: *https://www.mhtf.org/topics/maternal-health-in-the-united-states/*.

[883] Maternal Health in the United States. Maternal Health Task Force at the Harvard Chan School. Available at: *https://www.mhtf.org/topics/maternal-health-in-the-united-states/*.

[884] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. *American Journal of Obstetrics and Gynecology,* 215(3):B17.

[885] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. *American Journal of Obstetrics and Gynecology,* 215(3):B17–B22.

[886] Campbell, K.H.,Savitz, D.,Werner, E.F., Pettker, C.M., Goffman, D., Chazotte, C., Lipkind, H.S. (2013). Maternal Morbidity and Risk of Death at Delivery Hospitalization. *Obstetrics and Gynecology,* 122(3): 627–633. *https://journals.lww.com/greenjournal/fulltext/2013/09000/Maternal_Morbidity_and_Risk_of_Death_at_Delivery.20.aspx*.

[887] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. *American Journal of Obstetrics and Gynecology,* 215(3): B17.

[888] World Health Organization (WHO), Bulletin of the WHO. Maternal Mortality and Morbidity in the United States. Available at: *https://www.who.int/bulletin/volumes/93/3/14-148627/en/*.

[889] World Health Organization (WHO), Bulletin of the WHO. Maternal Mortality and Morbidity in the United States. Available at: *https://www.who.int/bulletin/volumes/93/3/14-148627/en/*.

[890] World Health Organization (WHO), Bulletin of the WHO. Maternal Mortality and Morbidity in the United States. Available at: *https://www.who.int/bulletin/volumes/93/3/14-148627/en/*.

1, 2021 through December 31, 2021, affecting the FY 2023 payment determination, to help address this maternal health crisis. After which, the reporting period will be 12 months beginning with the FY 2024 payment determination (reporting period January 1, 2022 through December 31, 2022) and for subsequent years. We developed this structural measure to determine hospital participation in a State or national Perinatal Quality Improvement (QI) Collaborative initiative and implementation of patient safety practices or bundles within that QI initiative. We define a State or national Perinatal Quality Improvement Collaborative as a Statewide or a multi-State network working to improve women's health and maternal health outcomes by addressing the quality and safety of maternity care. These collaboratives employ clinical practices and processes to address gaps in care, as well as collect and review performance data. These collaboratives also include implementation of evidence-based maternity safety bundles and/or patient safety practices to improve patient outcomes and reduce maternal mortality and severe maternal morbidity. Hospital participation in quality improvement collaboratives has been shown to be effective in appropriately managing maternal morbidity conditions that may lead to mortality or other adverse consequences.[891] This measure will: (1) Determine the number of hospitals currently participating in a structured State or national Perinatal QI Collaborative; and (2) determine whether hospitals are implementing the safety practices or bundles included as part of these QI initiatives.

State level QI programs have been shown to be effective in decreasing maternal morbidity.[892] One controlled trial conducted at 147 California hospitals utilizing a QI toolkit, which was a patient safety bundle for obstetrical hemorrhage, found that hospitals that had implemented the QI toolkit showed a 20.8 percent decrease in obstetrical hemorrhage versus a 1.2 percent reduction at non-participating hospitals.[893] We believe the Maternal Morbidity measure will help us better understand the current efforts of hospitals to improve nationwide inpatient maternal morbidity.

The existing literature on maternal morbidity also documents how patient safety practices and bundles utilized in Statewide and national Perinatal Quality Collaborative programs can improve maternal outcomes.[894] The implementation of triggers, bundles, protocols, and checklists have been shown to improve the quality and safety of obstetric care delivery.[895] Triggers are used to identify an event that mandates further action by a healthcare professional, which then facilitates timely intervention and patient safety.[896] Examples of triggers include hypertension greater than 180/110 and fever (temperature over 38.5 °C).[897] Bundles are a collection of interventions such as checklists, protocols, and educational materials that target a specific morbidity such as hypertension or hemorrhage.[898] Protocols are precise plans of action for specific clinical scenarios and serve to augment memory and limit human error in demanding environments such as labor and delivery units.[899] These evidence-based tools also facilitate improvements in timely diagnosis and treatment that serve to prevent morbidity.[900] This measure will allow us to assess hospital participation in QI collaborative programs in the inpatient setting and the implementation of safety practices or bundles.

At this time, CMS quality reporting programs do not include quality measures that specifically address maternal morbidity. The current Hospital IQR Program measure set includes the PC–01 measure for Elective Deliveries (77 FR 53530), and the Merit-Based Incentive Payment System (MIPS) in the Quality Payment Program includes measures for Elective Delivery or Early Induction and Post-Partum Follow-up and Care Coordination (81 FR 77625). While these measures contribute to improving maternal health, they do not specifically address maternal morbidity. Therefore, we believe it is important to adopt this measure into the Hospital IQR Program.

Under CMS' Meaningful Measures Framework, the Maternal Morbidity measure addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.'' [901] Because many of the factors contributing to maternal morbidity are preventable, this measure will be the first step toward assessing the current landscape of QI participation and implementation of patient safety practices or bundles with the objective of reducing maternal morbidity, and in turn, maternal mortality.

(2) Overview of Measure

To report on this measure, hospitals will respond to a two-part question: ''Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care, and has it implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?''

[891] Main, E.K., Cape, V., Abreo, A., Vasher, J., Woods, A., Carpenter, A., Gould, J.B. (2017). Reduction of Severe Maternal Morbidity from Hemorrhage Using a State Perinatal Quality Collaborative. *American Journal of Obstetrics and Gynecology,* 216(3): 298.e1. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/28153661.*

[892] Main, E.K., Cape, V., Abreo, A., Vasher, J., Woods, A., Carpenter, A., Gould, J.B. (2017). Reduction of Severe Maternal Morbidity from Hemorrhage Using a State Perinatal Quality Collaborative. *American Journal of Obstetrics and Gynecology,* 216(3): 298.e4. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/28153661.*

[893] Main, E.K., Cape, V., Abreo, A., Vasher, J., Woods, A., Carpenter, A., Gould, J.B. (2017). Reduction of Severe Maternal Morbidity from Hemorrhage Using a State Perinatal Quality Collaborative. *American Journal of Obstetrics and Gynecology,* 216(3): 298.e4. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/28153661.*

[894] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists—What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[895] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists—What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 449–450.

[896] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists—What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[897] Forster, Alan J. MD, FRCPC; Fung, Irene; Caughey, Sharon MD, FRCPC; Oppenheimer, Lawrence MD, FRCPC; Beach, Cathy; Shojania, Kaveh G. MD; van Walraven, Carl MD, FRCPC, MSc. 2006. Adverse Events Detected by Clinical Surveillance on an Obstetric Service. Obstetrics and Gynecology, 108(5): 1073–1083.

[898] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists—What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[899] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists—What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[900] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists—What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[901] The Maternal Morbidity Measure addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.'' More information on CMS' Meaningful Measures Framework is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

Hospitals will then choose from the following response options: (A) ''Yes''; (B) ''No''; or (C) ''N/A (our hospital does not provide inpatient labor/delivery care)'' and will submit responses once a year via a CMS-approved web-based tool on the QualityNet website.

The Maternal Morbidity measure was included on the publicly available ''2019 Measures under Consideration Spreadsheet'' [902] (MUC List), a list of measures under consideration for use in various Medicare programs. The Measure Applications Partnership (MAP) Hospital Workgroup, which the MAP Coordinating Committee oversees, reviewed the MUC List and the Maternal Morbidity measure (MUC2019–114) in detail on December 4, 2019.[903] The MAP Hospital Workgroup reviewed the measure as: ''Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care, which includes implementation of patient safety practices or bundles to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?'' [904] The MAP Hospital Workgroup's preliminary recommendation was to not support MUC2019–114 Maternal Morbidity for rulemaking, with potential for mitigation.[905]

The potential mitigating factors identified by the MAP Hospital Workgroup were to adjust the language of the question to clarify that the hospital is expected both to attest to participation in a quality improvement initiative as well as to implement patient safety practices or bundles to address complications and that the Maternal Morbidity measure go through the NQF endorsement process. The MAP Hospital Workgroup members suggested replacing ''which includes implementation of patient safety practices or bundles'' with ''and has implemented patient safety practices or bundles'' to clarify that the intent of the measure is both to identify hospitals that participate in a QI program *and* implement specific bundles known to improve outcomes.[906] To address the MAP's feedback regarding the measure's usability, we made the aforementioned change to the measure, thereby clarifying that the measure will assess participation in QI initiatives *and* the implementation of patient safety practices or bundles to address complications (rather than assessing participation in a QI initiative alone).

The MAP Coordinating Committee, which provides direction to the MAP workgroups, reconvened on January 15, 2020 and reviewed MUC2019–114 Maternal Morbidity measure for rulemaking in detail.[907] The MAP Coordinating Committee reviewed the measure as: ''Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care, and has implemented patient safety practices or bundles to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?'' [908] Upon the review of the measure, the MAP Coordinating Committee conditionally supported MUC2019–114 Maternal Morbidity for rulemaking.[909]

The conditions identified by the MAP Coordinating Committee included adjusting the language of the attestation question to clarify that the hospital is expected both to attest to participation in a quality improvement initiative as well as actually implement patient safety practices or bundles to address complications.[910] In response to this recommendation, we adjusted the language of the attestation to clarify that answering ''Yes'' to the attestation reflects a yes response to both components of the question.

The MAP Coordinating Committee included an additional condition that we allow multi-hospital quality improvement collaborative participation, in addition to Statewide or national collaboratives, to account for programs sponsored by large health systems.[911] We considered this, but ultimately concluded that those programs should not be included because they are not as well defined as State and national collaboratives.

The MAP Coordinating Committee also recommended adding information to the response options to clarify what constitutes a ''yes, no, or n/a'' response.[912] In response to this recommendation, we plan to include additional educational and clarifying detail on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). Such additional educational and clarifying detail would explain that a hospital participating in a Statewide or national Perinatal Quality Improvement (QI) Collaborative, such as the California Maternal Quality Care Collaborative or the Alliance for Innovation on Maternal Health (AIM) program, that has actively implemented patient care safety practices and/or bundles would select ''yes.'' A hospital that neither participates in a Statewide or national Perinatal QI Collaborative, such as those previously noted, nor has actively implemented patient safety care practices and/or bundles, would select ''no.'' A hospital that participates in a Statewide or national Perinatal QI Collaborative, but has not actively implemented patient care safety practices and/or bundles would select ''no.'' Hospitals that do not provide inpatient labor and delivery care services would select ''n/a.''

Lastly, the MAP Coordinating Committee added a condition that the Maternal Morbidity measure should go through the NQF endorsement process

[902] 2019 Measures Under Consideration. Information available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91406.*

[903] National Quality Forum. Measure Applications Partnership (MAP) 2020 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *qualityforum.org/map/.*

[904] National Quality Forum. Measure Applications Partnership (MAP) 2020 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *qualityforum.org/map/.*

[905] National Quality Forum. Measure Applications Partnership (MAP) 2020 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *qualityforum.org/map/.*

[906] National Quality Forum. Measure Applications Partnership (MAP) 2020 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *qualityforum.org/map/.*

[907] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[908] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[909] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[910] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[911] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[912] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

and receive endorsement.[913] The MAP Coordinating Committee underscored that maternal morbidity is increasing at an alarming rate in the U.S., nearly doubling in the last decade.[914] With no quality measures that address maternal morbidity, the MAP Coordinating Committee supported our attempts to address this healthcare crisis through measurement.[915]

Section 1886(b)(3)(B)(IX)(bb) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures that addressed maternal morbidity through hospital participation in State or national perinatal quality collaboratives and the implementation of associated bundles or practices. We found no other feasible and practical measures on the topic of maternal health, therefore we believe the exception in Section 1886(b)(3)(B)(IX)(bb) of the Act applies.

(3) Data Submission and Reporting

We proposed to begin with a shortened reporting period before transitioning to full year reporting periods to get a preliminary gauge of hospital participation in QI initiatives in a timely manner. Specifically, for the CY 2021 reporting period/FY 2023 payment determination, we proposed a shortened reporting period: October 1, 2021 through December 31, 2021. Beginning with the CY 2022 reporting period/FY 2024 payment determination and for subsequent years, we proposed that the reporting period will be: January 1 through December 31.

We proposed to collect this data once a year via a CMS-approved web-based data collection tool available on the QualityNet website, similar to previous methods of reporting on structural measures. Specifications for the measure will also be posted on the CMS Measure Methodology page with the file name 'Maternal Morbidity Structural Measure Specifications' at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*. We refer readers to section IX.C.9.i. of the preamble of this final rule for more details on our data submission and deadline requirements for structural measures.

We invited public comment on this proposal.

Comment: Several commenters supported adoption of the Maternal Morbidity structural measure for the Hospital IQR Program. Specifically, several commenters noted that a gap in quality improvement for the maternal setting currently exists and expressed appreciation for CMS' initiative to combat maternal morbidity. A commenter specifically expressed their appreciation of the alignment of the measure requirements with the Centers for Disease Control and Prevention (CDC) Alliance for Innovation on Maternal Health (AIM) bundles.

Response: We thank the commenters for their support of the Maternal Morbidity structural measure and agree that improving maternal health is a priority and a quality improvement goal for CMS.

Comment: Many commenters suggested updates to the proposed measure specifications, including: (1) Capturing specific safety practices; (2) collecting sociodemographic data to allow for measuring racial and ethnic disparities in maternal morbidity rates; (3) using electronic reporting instead of an attestation; and (4) revising the attestation question. A commenter sought clarification on whether the Maternal Morbidity structural measure would focus on investments in and resources dedicated to breastfeeding.

Response: We thank commenters for their recommendations on changes to the measure specifications. While we agree that many types of patient safety and quality improvement initiatives are important to improving patient care, the standards and comprehensiveness of such initiatives can vary widely. We have therefore determined that this measure will focus on whether hospitals work with official Statewide or national Perinatal QI Collaboratives which meet certain standards. We wish to clarify that the proposed Maternal Morbidity structural measure does address breastfeeding. It focuses on determining hospital participation in a Statewide or national Perinatal QI Collaborative and implementation of patient safety practices or bundles within that QI collaborative, which includes breastfeeding. We appreciate commenters interest in electronic data submission. Hospitals will be required to submit their responses to the two-part question using a web-based tool via CMS' Hospital Quality Reporting (HQR) system (formerly referred to as the QualityNet system or QualityNet Secure Portal). We are adopting the measure with the stated attestation question, as proposed,[916] because we believe it is critical for hospitals to both participate in a QI collaborative and take action to implement appropriate safety protocols. CMS will consider future changes to the measure during ongoing measure maintenance.

Comment: A few commenters sought clarification on participating in a Statewide or national Perinatal QI Collaborative, more specifically, which programs would count towards participation in a Statewide or national Perinatal QI Collaborative and recommended broadening the definition to include quality initiatives related to patient safety organizations. A commenter recommended that we include birth equity collaboratives to quality initiatives and others suggested that we include an avenue for patient and community engagement with quality improvement initiatives. A few commenters stated that it may be difficult for some facilities to attest ''Yes'' to the measure given that there may be volume limits on participation in quality improvement programs for hospitals.

Response: We appreciate commenters' comments about Statewide or national Perinatal QI Collaboratives. Stakeholders seeking further clarification on which Statewide or national Perinatal QI Collaboratives will be participating can view additional education and clarifying program details that will be provided on the QualityNet website (also referred to as the Hospital Quality Reporting (HQR) system) at: *http://www.QualityNet.cms.gov* (or other successor CMS designated websites). With regards to broadening the types of initiatives included in the measure (such as those related to patient safety organizations, birth equity collaboratives, or community engagement initiatives), while we agree that many types of patient safety and quality improvement initiatives are

[913] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[914] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[915] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[916] We have added the word 'it' to the Maternal Morbidity measure attestation question, which is a non-substantive addition and does not change the meaning or context.

important to improving patient care, the standards and comprehensiveness of such initiatives can vary widely. We have therefore determined that this measure will focus on whether hospitals work with official Statewide or national Perinatal QI Collaboratives which meet certain standards. We are not aware of volume limits on participation in quality improvement programs for hospitals and we encourage stakeholders to inform us if that becomes a specific issue. We note that even if participation in a Statewide Perinatal QI Collaborative is capped, a number of national Perinatal QI Collaboratives are available, such that we do not anticipate hospitals being unable to participate due solely to volume limits. In addition, we highlight that the Hospital IQR Program is a pay-for-reporting program, and hospitals are not scored based on their performance on measures.

Comment: Several commenters encouraged CMS to submit the Maternal Morbidity structural measure to the National Quality Forum (NQF) for endorsement. Commenters in favor of NQF endorsement stated that the Maternal Morbidity structural measure would have greater potential to make lasting impacts in reducing maternal morbidity if endorsed by NQF. A commenter expressed that they would like to see the Maternal Morbidity structural measure eventually evolve into a quality outcome measure.

Response: We thank commenters for their recommendations. While we recognize the value of measures undergoing NQF endorsement review, given the severity of the maternal morbidity crisis and, as there are currently no NQF-endorsed measures that address maternal morbidity through hospital participation in Statewide or national Perinatal QI Collaboratives, we believe it is important to implement this measure as soon as possible. As noted above, per section 1886(b)(3)(B)(IX)(bb) of the Act, NQF endorsement is not a prerequisite for adoption of a measure into the Hospital IQR Program. In addition, we support the development of quality outcome measures addressing maternal morbidity and are considering new eCQMs in development focused on severe obstetrics complications.

Comment: Many commenters had concerns regarding the measure's initial reporting period starting on October 1, 2021. A commenter recommended using the initial reporting period for informational purposes only and not for use in the Hospital IQR Program. Several commenters requested that CMS delay implementation of the Maternal Morbidity structural measure to allow hospitals additional time to research collaborative programs and prepare for accurate reporting, and a commenter noted that a delay would give localities time to launch perinatal quality collaboratives (PQC) or Alliance for Innovation on Maternal Health (AIM) bundles. A few commenters noted that starting reporting so abruptly could lead to reliability concerns in the data due to misreporting and could potentially lead to other unintended consequences. Another commenter expressed concern that not all participating States have implemented perinatal quality collaboratives (PQC).

Response: We appreciate commenters' concerns about the initial reporting period, however, we believe that maternal morbidity is a pressing issue which deserves serious focus and rapid action for maternal health improvement. We note that the Maternal Morbidity structural measure is being adopted for the Hospital IQR Program at this time, meaning hospitals will receive credit for the reporting of their measure results, regardless of their responses to the attestation question. Use of this measure in the Hospital IQR Program will provide useful information to CMS and the public on the number of hospitals currently participating in structured Statewide or national Perinatal QI Collaboratives and implementing the safety practices. With regards to commenters' concerns that beginning reporting as soon as the FY 2023 payment year could lead to misreporting or unintended consequences, we believe collecting data and reporting results for this measure right away will provide a critical baseline and we will monitor the data and any unintended consequences of the measure as part of standard measure maintenance. In locations where a Statewide collaborative is not yet launched, hospitals may choose to participate in a national collaborative for the Maternal Morbidity structural measure.

Comment: Several commenters did not support the adoption of a Maternal Morbidity structural measure. Commenters felt there was a lack of evidence supporting the relationship between participation in Statewide or national Perinatal QI Collaboratives and improved outcomes, and therefore, questioned the value and usefulness of the structural measure on reducing maternal morbidity or informing patient decision-making on where to receive care.

Response: We respectfully disagree that the proposed structural measure lacks value. We believe this measure serves as a key first step in measuring and promoting quality improvement by encouraging hospitals to collaborate with QI organizations and implement safety protocols.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

b. Adoption of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure With Claims and Electronic Health Record Data (NQF#3502) Voluntary From July 1, 2022 Through June 30, 2023, and Mandatory Beginning July 1, 2023 Through June 30, 2024, Affecting the FY 2026 Payment Determination and Subsequent Years

(1) Background

Estimates using data from 2008 to 2011 suggest that more than 210,000 patients die each year from preventable harm in hospitals.[917] While we do not expect overall hospital mortality rates to be zero, studies have shown that quality of care relates to mortality within 30 days of hospital admission and that high and variable mortality rates across hospitals indicate opportunities for improvement.[918] [919] In addition to the harm to individuals, their families, and caregivers resulting from preventable death, there are also significant financial costs to the healthcare system associated with high and variable mortality rates.[920] [921] [922] While capturing monetary savings for preventable mortality events is challenging, using two recent estimates of the number of deaths due to preventable medical errors, and assuming an average of 10 lost years of life per death (valued at $75,000 per year in lost quality adjusted life years), the annual direct and indirect cost of potentially preventable deaths could be

[917] James JT. A new, evidence-based estimate of patient harms associated with hospital care. *Journal of patient safety.* 2013; 9(3):122–128.

[918] Peterson ED, Roe MT, Mulgund J, et al. Association between hospital process performance and outcomes among patients with acute coronary syndromes. *JAMA.* 2006; 295(16):1912–1920.

[919] Writing Group for the Checklist- I.C.U. Investigators, Brazilian Research in Intensive Care Network. Effect of a quality improvement intervention with daily round checklists, goal setting, and clinician prompting on mortality of critically ill patients: A randomized clinical trial. *JAMA.* 2016; 315(14):1480–1490.

[920] Institute of Medicine 2000. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press. Available at: *https://www.nap.edu/resource/9728/To-Err-is-Human-1999—report-brief.pdf.*

[921] Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. Health Affairs. 2011; 30(4):581–589.

[922] Andel C, Davidow SL, Hollander M, Moreno DA. The economics of health care quality and medical errors. *Journal of health care finance.* 2012; 39(1):39–50.

as much as $73.5 to $735 billion.[923] [924] [925]

Condition-specific mortality measures previously adopted into the Hospital IQR and Hospital VBP Programs support quality improvement work targeted toward patients with a set of common medical conditions, such as stroke, heart failure, acute myocardial infarction, or pneumonia. Following the implementation of condition-specific measures, national hospital mortality rates for the measured conditions and/or procedures have declined.[926] Now, we are interested in also measuring hospital performance across a broader set of patients and across more areas of the hospital.

We developed a hybrid hospital-wide, all-cause, risk-standardized mortality measure that uses claims data to define the measure cohort and a combination of data from electronic health records (EHRs) and claims for risk adjustment (Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (hereinafter referred to as the ''Hybrid HWM measure'')). As more patients are included, a hospital-wide mortality measure also captures the performance for smaller volume hospitals that would otherwise not have sufficient cases to receive measure score or performance information for condition- or procedure-specific mortality measures. As developed, the Hybrid HWM measure addresses the Meaningful Measures Framework quality priority of ''Promoting Effective Treatment to Reduce Risk-Adjusted Mortality.''

The measure developer under contract with us engaged several stakeholder groups, including a Technical Work Group and a Patient and Family Work Group, as well as a national, multi-stakeholder Technical Expert Panel (TEP) consisting of providers, patients, and other stakeholders. These groups provided feedback on the measure concept, outcome, cohort, risk model variables, and the reporting of measure results. The measure developer also solicited stakeholder feedback during measure development as required in the Measures Management System (MMS) Blueprint, including two public comment periods.[927]

The Hybrid HWM measure uses claims and EHR data to move toward greater use of EHR data for quality measurement. This approach aligns with stakeholder feedback on the importance of including clinical data that is available to the clinical care team at the time treatment is rendered to account for patients' severity of illness, rather than relying solely on data from claims in outcome measures (80 FR 49702 through 49703). This approach also aligns with our goal to move towards digital quality measures (dQMs) to reduce provider data collection burden and to provide more rapid performance feedback on quality measures, as discussed further in section IX.A. of the preamble of this final rule.

The Hybrid HWM measure uses a set of core clinical data elements from hospitals' EHRs, similar to those used in the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879), which was adopted in the Hospital IQR Program in the FY2020 IPPS/LTCH PPS final rule (84 FR 42467). These core clinical data elements are data that hospitals routinely collect, that can be feasibly extracted from hospital EHRs, and that can be utilized as part of specific quality outcome measures.[928] The data elements are the values for a set of vital signs and common laboratory tests collected at the time the patient initially presents to the hospital. They are used, in addition to claims data, for risk adjustment of patients' severity of illness (for Medicare FFS beneficiaries who are aged between 65 and 94 years). We refer readers to section IX.C.5.b.(7). of the preamble of this final rule for more detail on the core clinical data elements used in this measure.

The Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (MUC17–196) was included in a publicly available document entitled ''2017 Measures Under Consideration List'' (available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86527*). The NQF MAP Hospital Workgroup reviewed the measure and noted that it is an important measure for patient safety and that the measure could help reduce deaths due to medical errors.[929] The MAP expressed concern regarding the potential unintended consequences of unnecessary interventions for patients at the end of life.[930] The measure developer addressed this issue based upon TEP and patient work group input to remove patients from the cohort who are at the end of life and for whom survival is unlikely to be the goal of care. Specifically, the measure does not include patients enrolled in hospice in the 12 months prior to admission, on admission, or within 2 days of admission. The measure also does not include patients admitted primarily for cancer that are enrolled in hospice at any time during the admission, those admitted primarily for metastatic cancer, and those admitted for specific diagnoses with limited survival.

The MAP additionally requested that the NQF assess whether the measure has appropriate clinical and social risk factors in its risk adjustment model and addresses necessary exclusions. The MAP noted that appropriate risk adjustment and exclusions are necessary to ensure the measure does not disproportionately penalize facilities who may see more complex patients (for example, academic medical centers or safety net providers) or who may have smaller volumes of patients (for example, rural providers). We subsequently submitted the measure for initial endorsement by the NQF and presented analyses to NQF on the impact of social risk factors. Specifically, we assessed the relationship between two social risk factor variables (Medicare-Medicaid dual-eligibility status and the AHRQ-validated socioeconomic status (SES) index score) and the outcome (mortality). We also examined the effect of adding either of these variables into the risk adjustment model on model performance and hospital results. We concluded that correlations between measure scores for models with and

[923] Institute of Medicine 2000. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press. *https://www.nap.edu/resource/9728/To-Err-is-Human-1999—report-brief.pdf.*

[924] Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. Health Affairs. 2011; 30(4):581–589.

[925] Andel C, Davidow SL, Hollander M, Moreno DA. The economics of health care quality and medical errors. *Journal of health care finance.* 2012; 39(1):39–50.

[926] Suter LG, Li SX, Grady JN, et al. National patterns of risk-standardized mortality and readmission after hospitalization for acute myocardial infarction, heart failure, and pneumonia: Update on publicly reported outcomes measures based on the 2013 release. *Journal of general internal medicine.* 2014; 29(10):1333–1340.

[927] CMS Measures Management System Blueprint (Blueprint v 16.0). CMS. 2020 . Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[928] 2013 Core Clinical Data Elements Technical Report (Version 1.1). 2015. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.* Accessed January 2021.

[929] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083.*

[930] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083.*

without social risk variables were near 1.0, model performance metrics were unchanged, and in most divisions the social risk variables did not have statistically significant association with the risk of mortality in a multivariable model. For the division in which AHRQ SES was associated with mortality, further analyses indicated that adjusting for AHRQ SES would remove hospital-level effects that may reflect lower-quality care provided to patients with low SES status. Based on these results, the measure as endorsed by NQF does not adjust for these social risk factors. The measure is risk-adjusted to account for case mix and service mix differences to prevent disproportionately penalizing facilities.[931] NQF fully reviewed the measure, including risk adjustment, and endorsed the measure with the risk adjustment, as specified. As presented to NQF, we also noted that all exclusions were determined by careful clinical review and have been made based on clinically relevant decisions and to ensure accurate calculation of the measure. The NQF assessed the exclusions and supported the measure for endorsement.[932]

The MAP noted this measure used EHR data to support additional factors in the risk adjustment model. Given the variability in EHR systems, the MAP recommended that the NQF standing committee reviewing the measure pay special attention to the ability to consistently obtain EHR data across hospitals. We approached risk variable selection from the perspective of ensuring a parsimonious list of clinical EHR variables that would minimize hospital burden to report the data and provide face validity from a clinical perspective. As candidate risk variables, the core clinical data elements (CCDE) are consistently captured, captured with a standard definition, and entered into the electronic health record in a structured field and can be feasibly extracted, as shown during development and testing, and subsequently presented to NQF.[933]

The MAP further suggested that condition-specific mortality measures may be more actionable for providers and informative for consumers.[934] We note that by adopting the Hybrid HWM measure, we intend to offer additional benefits when reported with condition- or procedure-specific measures, such as: (1) Providing scores and performance information for smaller hospitals; (2) providing an overall hospital-level signal for consumers; and (3) providing yearly updates using a 1-year measurement period, unlike condition- or procedure-specific measures that use 3 years of claims data. Upon review, the MAP expressed their conditional support for rulemaking pending endorsement from the NQF.[935] Thereafter, the NQF endorsed the Hybrid HWM measure on October 23, 2019.[936] The MAP also recommended the Hybrid HWM measure have a voluntary reporting period before mandatory implementation.[937] Our finalized proposal to adopt the Hybrid HWM measure includes beginning with a 1-year voluntary reporting period, as further detailed later in section IX.C.5.b.(9).(a). of this final rule.

In the FY 2019 IPPS/LTCH PPS final rule, we described the potential future inclusion of the Hybrid HWM measure in the Hospital IQR Program and requested public feedback on the measure. Many stakeholders expressed support for the measure, with many commenters commending the use of EHR data. CMS also responded to stakeholder feedback on the measure methodology, validity, and concept (83 FR 41581 through 41588).

(2) Overview of Measure

The Hybrid HWM measure is an outcome measure that captures hospital-level, risk-standardized mortality within 30 days of hospital admission for most conditions or procedures. It does not have a traditional numerator and denominator like a core process measure (for example, percentage of adult patients with diabetes aged 18 to 75 years receiving one or more hemoglobin A1c tests per year). The measure is reported as a single summary score, derived from the results of risk-adjustment models for 15 mutually exclusive service-line divisions (categories of admissions grouped based on similar discharge diagnoses or procedures), with a separate risk model for each of the 15 service-line divisions. The 15 service-line divisions include: nine non-surgical divisions and six surgical divisions. The non-surgical divisions are: Cancer; cardiac; gastrointestinal; infectious disease; neurology; orthopedics; pulmonary; renal; and other. The surgical divisions are: Cancer; cardiothoracic; general; neurosurgery; orthopedics; and other. Hospitalizations are eligible for inclusion in the measure if the patient was hospitalized at a non-Federal, short-term acute care hospital; results will be publicly reported as part of the Hospital IQR Program.

To compare mortality performance across hospitals, the measure accounts for differences in patient characteristics (patient case mix) as well as differences in the medical services provided and procedures performed by hospitals (hospital service mix). In addition, the Hybrid HWM measure employs a combination of administrative claims data and clinical EHR data to enhance clinical case mix adjustment with additional clinical data. As described previously, the measure is reported as a single summary score, derived from the results of risk-adjustment models for 15 mutually exclusive service-line divisions. The overall risk-standardized mortality rate (measure score) will not always reflect a result from each of the 15 divisions for hospitals that do not have a sufficient number of admissions for each service-line division. As a result, some hospitals' overall scores would be based on fewer than 15 divisions because of differences in their case mix.

Our goal is to more comprehensively measure the mortality rates of hospitals, including to improve the ability to measure mortality rates in smaller volume hospitals. The cohort definition attempts to capture as many admissions as possible for which survival would be a reasonable indicator of quality and for which adequate risk adjustment is possible. We assume survival would be a reasonable indicator of quality for admissions fulfilling two criteria: (1) Survival is presumably the primary goal of the patient when they enter the hospital; and (2) the hospital can reasonably influence the patient's chance of survival through quality of care. The Hybrid HWM measure would provide information to hospitals that

[931] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083.*

[932] National Quality Forum. Available at: *https://www.qualityforum.org/QPS/3502.*

[933] 2013 Core Clinical Data Elements Technical Report (Version 1.1). 2015; *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.* Accessed January 2021.

[934] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083.*

[935] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083.*

[936] National Quality Forum. Available at: *https://www.qualityforum.org/QPS/3502.*

[937] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083.*

can facilitate quality improvement efforts and would expand upon condition- and procedure-specific measures by including more settings, types of care, and types of patients. In addition, the Hybrid HWM measure would provide transparency about the quality of care in clinical areas not captured in the current condition- and procedure-specific measures.

Additional information on the specifications of the Hybrid HWM measure can be found in the Core Clinical Data Elements and Hybrid Measure folder on the CMS website at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* and on the eCQI resource center website at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*.[938]

(3) Data Sources

The Hybrid HWM measure uses three main sources of data for the calculation of the measure: (1) Medicare Part A claims data; (2) a set of core clinical data elements from a hospital's EHR; and (3) mortality status obtained from the Medicare Enrollment Database. The measure uses claims and enrollment data to identify index admissions included in the Hybrid HWM measure cohort, in the risk-adjustment model, and to assess the 30-day mortality outcome. The measure uses one year of Part A Medicare administrative claims data from Medicare FFS beneficiaries aged between 65 and 94 years for the performance period. The measure uses Part A data from the 12 months prior to the index admission for risk adjustment, as well as core clinical data elements from each hospital's EHR for eligible patient admissions. The core clinical data elements are the values for a set of vital signs and common laboratory tests collected on patients admitted to acute care hospitals. The measure also requires a set of linking variables that are present in both the EHR and claims data, which allows us to match each patient's core clinical data elements to the claim for the relevant admission. We refer readers to the methodology report available on the CMS website for the list of linking variables and more detailed discussion.

(4) Outcome

The outcome of interest for the Hybrid HWM measure is all-cause 30-day mortality. We define all-cause mortality as death from any cause within 30 days of the index hospital admission date.

(5) Cohort

The Hybrid HWM measure cohort consists of Medicare FFS beneficiaries, aged between 65 and 94 years, discharged from a non-Federal, short-term acute care hospital, within the 1-year measurement period (July 1 to June 30 of each year). The measure was developed using ICD–9 codes, and then re-specified and re-tested using ICD–10 data. The Hybrid HWM measure cohort uses the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) [939] to group numerous diagnostic and procedural ICD–10 codes into the clinically meaningful categories defined by the AHRQ grouper. We made modifications to these AHRQ CCSs based on risk of mortality, as described in the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0.[940] The Hybrid HWM measure uses those CCS categories as part of cohort specification and risk-adjustment, including the 15 service-line risk models.

For the AHRQ CCSs and individual ICD–10–CM codes that define the measure development cohort, we refer readers to the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0.[941]

(6) Inclusion and Exclusion Criteria

The Hybrid HWM measure cohort currently includes Medicare FFS patients who—

- Were enrolled in Medicare FFS Part A for the 12 months prior to the date of admission and during the index admission;
- Have not been transferred from another inpatient facility;
- Were admitted for acute care (do not have a principal discharge diagnosis of a psychiatric disease or do not have a principal discharge diagnosis of ''rehabilitation care; fitting of prostheses and adjustment devices'');
- Are between 65 and 94 years of age;
- Are not enrolled in hospice at the time of or in the 12 months prior to their index admission;
- Are not enrolled in hospice within 2 days of admission;
- Are without a principal diagnosis of cancer and enrolled in hospice during their index admission;
- Are without any diagnosis of metastatic cancer; and
- Are without a discharge diagnosis that is present on admission (POA) for a condition for which hospitals have limited ability to influence survival, including: Anoxic brain damage; persistent vegetative state; prion diseases such as Creutzfeldt-Jakob disease, Cheyne-Stokes respiration; brain death; respiratory arrest; or cardiac arrest without a secondary diagnosis of acute myocardial infarction.

The measure currently excludes any of the following index admissions for patients:

- With inconsistent or unknown vital status;
- Discharged against medical advice;
- With an admission for crush injury, burn, intracranial injury, skull and face fractures, open wounds of head, neck, and trunk, or spinal cord injury; or
- With an admission in a low-volume CCS (within a particular service-line division), defined as equal to or less than 100 patients with that principal diagnosis across all hospitals.

The Hybrid HWM measure assigns each index admission to one of the mutually exclusive service-line divisions. For details on how each admission is assigned to a specific service-line division, and for a complete description and rationale of the inclusion and exclusion criteria, we refer readers to the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0.[942]

(7) Risk Adjustment

The Hybrid HWM measure adjusts for both case mix differences (clinical status

[938] We note that while the above link will allow readers to access the information, the following link is a more direct approach: *https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/1/cms844v2?qt-tabs_pre_rule_measure=0.*

[939] Clinical Classifications Software Refined (CCSR) *https://www.hcup-us.ahrq.gov/toolssoftware/ccsr/ccs_refined.jsp.*

[940] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[941] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[942] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

of the patient, accounted for by adjusting for age and comorbidities) and service mix differences (the types of conditions and procedures cared for and procedures conducted by the hospital, accounted for by the discharge CMS condition category and AHRQ CCS). Patient comorbidities are based on inpatient hospital administrative claims during the 12 months prior to and including the index admission derived from ICD–10 codes grouped into the CMS condition categories (CMS–CCs). Risk variable coefficients vary by service-line division. We used version 22 [943] [944] of the CMS–CC map (for more information about our risk-adjustment model software, we refer readers to the Risk Adjustment page on the CMS website at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html*.)

The Hybrid HWM measure also includes the core clinical data elements in the case mix adjustment. The core clinical data elements are values for lab values and vital signs derived from information captured in the EHR during the index admission only, as described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49699). The core clinical data elements are clinical information meant to reflect a patient's clinical status upon arrival to the hospital. The table lists the 10 specific elements used in the proposed Hybrid HWM measure.

Currently Specified Core Clinical Data Element Variables

Data Elements	Units of Measurement	Time Window for First Captured Values
Heart Rate	Beats per minute	0-2 hours
Systolic Blood Pressure	mmHg	0-2 hours
Temperature	Degrees (Fahrenheit or Celsius)	0-2 hours
Oxygen Saturation	Percent	0-2 hours
Hematocrit	Percent	0-24 hours
Platelet	Count	0-24 hours
White Blood Cell Count	10^9 per liter (X10E+09/L)	0-24 hours
Sodium	mmol/L	0-24 hours
Bicarbonate	mmol/L	0-24 hours
Creatinine	mg/dL	0-24 hours

The core clinical data elements utilize EHR data, therefore, using the Measure Authoring Tool (MAT)—a web-based tool that allows the authoring of eCQMs using a standardized data model and Clinical Quality Language (CQL) expressions [945]—we developed and tested a MAT output and identified value sets for extraction of the core clinical data elements, which are available at the eCQI Resource Center: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*. For more details on how the risk variables in each measure were chosen, we refer readers to the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0.[946]

The proposed Hybrid HWM measure was initially specified to use core clinical data elements that are similar to, but not precisely the same as, those used in the Hybrid Hospital-Wide Readmission Measure (Hybrid HWR measure) with Claims and Electronic Health Record Data measure (NQF #2879), for which we are currently collecting data from hospitals on a voluntary basis through June 30, 2023 (84 FR 42465). Since the Hybrid HWM measure was described in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41581 through 41588), we have updated the core clinical data elements for the Hybrid HWM measure to include hematocrit instead of hemoglobin to better align with the Hybrid HWR measure. Hemoglobin and hematocrit values are highly correlated and interchangeable with respect to their impact in the Hybrid HWM measure's risk model. The Pearson correlation coefficients of hemoglobin to hematocrit ranged from 0.88–0.97, depending on service-line division. We believe this alignment will increase the ease of reporting on both measures.

With this update, hospitals will already collect nine of the ten core clinical data elements used in the Hybrid HWM measure for reporting on the Hybrid HWR measure, with platelets being the only additional data element used specifically for the Hybrid HWM measure. For more detail about the core clinical data elements used in the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data measure (NQF #2879), we refer readers to our discussion in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465 through 42479) and the Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors report (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.)

We will update the measure specifications annually for the measure to incorporate new and revised ICD–10 codes effective October 1 of each year after clinical review as necessary. We

[943] Pope GC, Ellis RP, Ash AS, et al. Diagnostic cost group hierarchical condition category models for Medicare risk adjustment. Final Report to the Health Care Financing Administration under Contract Number 500–95–048. 2000; *http://www.cms.hhs.gov/Reports/downloads/pope_2000_2.pdf*. Accessed February 25, 2020.

[944] Pope GC, Kautter J, Ingber MJ, et al. Evaluation of the CMS–HCC Risk Adjustment Model: Final Report. 2011; *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/evaluation_risk_adj_model_2011.pdf*. Accessed February 25, 2020.

[945] The Measure Authoring Tool (MAT) is a publicly available, web-based tool for measure developers to create eMeasures. The MAT now operates under the direction of the Centers for Medicare and Medicaid Services. For more information on the MAT, please visit: *www.emeasuretool.cms.gov*.

[946] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

will also update and publicly release the MAT output annually as necessary to include any updates to the electronic specifications, which includes value sets for the measure-specific data elements.

(8) Measure Calculation

Index admissions are assigned to one of 15 mutually exclusive service-line divisions consisting of related conditions or procedures. For each service-line division, the standardized mortality ratio (SMR) is calculated as the ratio of the number of ''predicted'' deaths to the number of ''expected'' deaths at a given hospital. In other words, for each hospital, the numerator of the ratio is the number of deaths within 30 days predicted based on the hospital's performance with its observed case mix and service mix, and the denominator is the number of deaths expected based on the nation's performance with that hospital's case mix and service mix. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses.

A hospital-wide composite SMR is then created by pooling the service-line SMRs for each hospital using an inverse variance-weighted mean. The inverse variance-weighted mean can be interpreted as a weighted average of all SMRs that takes into account the precision of SMRs. To produce the RSMR, the composite SMR is multiplied by the national observed mortality rate. For additional details regarding the measure specifications to calculate the RSMR, we refer readers to the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors: Measure Methodology Report Version 2.0.[947]

We also note an important distinguishing factor about hybrid measures as compared to eCQMs: CMS must calculate hybrid measure results to determine hospitals' risk-adjusted rates relative to national rates using data from all reporting hospitals. With a hybrid measure, hospitals submit data extracted from the EHR, and CMS performs the measure calculations and disseminates results.

During development and testing of the Hybrid HWM measure, we demonstrated that the core clinical data elements were feasibly extracted from hospital EHRs. We also demonstrated that the use of the core clinical data elements to risk-adjust the Hybrid HWM measure results in excellent discrimination (as in, the ability to distinguish patients with a low risk of mortality from those at high risk of mortality) of the measure, as assessed by the c-statistic. C-statistics ranged from 0.82 to 0.95, depending on the service line division. The adjusted intraclass correlation coefficient (ICC), which assesses reliability of the RSMR, also demonstrated high reliability at 0.7748.[948]

(9) Data Submission

(a) Reporting and Submission Timeframes for Proposed Voluntary and Mandatory Reporting Periods

For this measure, we will start with voluntary reporting in response to the MAP recommendation before requiring data submission. We believe that taking an incremental approach to implementing this measure will allow hospitals more time to update and validate their systems, to ensure data mapping is accurate and complete, to implement workflow changes as necessary to better prepare for submitting data, and to increase familiarity with data submission for hybrid quality measures when the Hybrid HWM measure becomes required. We proposed a stepwise approach in which we would first accept data submissions for the Hybrid HWM measure during a voluntary reporting period. In this period, we will collect data on the Hybrid HWM measure in accordance with, and to the extent permitted by, the HIPAA Privacy and Security Rules (45 CFR parts 160 and 164, Subparts A, C, and E), and other applicable law. This voluntary reporting period will include four quarters of data. Specifically, the voluntary reporting period will run from July 1, 2022 through June 30, 2023. Hospitals that elect to submit data should do so according to the requirements described in this section and in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58940 through 58942). Under previously established policy, hospitals must submit the core clinical data elements and linking variables within 3 months following the end of the applicable reporting period (submissions are required no later than the first business day 3 months following the end of the reporting period).

Mandatory reporting will begin with the reporting period which runs from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years. Hospitals will be required to submit the core clinical data elements and linking variables within 3 months following the end of the applicable reporting period (submissions will be required no later than the first business day 3 months following the end of the reporting period). This mandatory reporting period for the Hybrid HWM measure aligns with that of the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) that was finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465 through 42479).

Notably, while we finalized two voluntary reporting periods for the Hybrid Hospital-Wide Readmission measure (84 FR 42465 through 42479), we only proposed to have one voluntary reporting period for the Hybrid HWM measure, which will coincide with the second voluntary reporting period for the Hybrid Hospital-Wide Readmission measure. We believe one voluntary reporting period is sufficient for the Hybrid HWM measure because hospitals will already have two separate opportunities to learn how to report the core clinical data elements for the Hybrid Hospital-Wide Readmission measure, which mostly align with the Hybrid HWM measure core clinical data elements as described previously. Therefore, hospitals will have the opportunity to familiarize themselves with the reporting requirements and process for the core clinical data elements prior to the Hybrid HWM measure voluntary reporting period.

(b) File Type

Beginning with the proposed voluntary reporting period using data from July 1, 2022 through June 30, 2023, we proposed that hospitals use Quality Reporting Data Architecture (QRDA) Category I files for each Medicare FFS beneficiary aged between 65 and 94 years. Submission of data to CMS using QRDA I files is the current EHR data and measure reporting standard adopted for eCQMs implemented in the Hospital IQR Program (84 FR 42506, 85 FR 58940). This same standard will be used for reporting the core clinical data elements to the CMS data receiving system via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). Specifically, to successfully submit the Hybrid HWM measure, hospitals will need to submit the core clinical data elements included in the Hybrid HWM measure, as

[947] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[948] Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics.* 1977:159–174.

described in the measure specifications, for all Medicare FFS beneficiaries aged between 65 and 94 years discharged from an acute care hospitalization in the 1-year measurement period (July 1 to June 30 of each year). We note this aligns with the measurement period for the Hybrid HWR measure (84 FR 42465 through 42479).

(c) Data Thresholds

For us to be able to calculate the Hybrid HWM measure results, each hospital will need to report vital signs for 90 percent or more of the hospital admissions for Medicare FFS patients, aged between 65 and 94 years old discharged in the measurement period (as determined from the claims submitted to CMS for admissions that ended during the same reporting period). Vital signs are measured on nearly every adult patient admitted to an acute care hospital and should be present for nearly 100 percent of discharges (identified in Medicare FFS claims submitted during the same period). In addition, calculating the measure with more than 10 percent of hospital discharges missing these data elements could cause poor reliability of the measure score and instability of hospitals' results from measurement period to measurement period.

Hospitals will also need to report the laboratory test results for 90 percent or more of hospital admissions for nonsurgical patients, meaning those not included in the surgical divisions of the Hybrid HWM measure. For many patients in the surgical divisions admitted following elective surgery, there are no laboratory values available in the appropriate time window. Therefore, there is no submission requirement for the surgical divisions. However, hospitals should submit lab values for those patients in surgical divisions with lab values available within the appropriate time window. Laboratory values submitted will be included in the risk adjustment model.

(d) Linking Variables and Other Data Elements

Hospitals will also be required to successfully submit the following six linking variables that are necessary in order to merge the core clinical data elements with the CMS claims data to calculate the measure:

- CMS Certification Number;
- Health Insurance Claims Number or Medicare Beneficiary Identifier;
- Date of birth;
- Sex;
- Admission date; and
- Discharge date.

The six linking variables required for linking EHR and claims data should be routinely captured and available for nearly every adult patient admitted to an acute care hospital.

Because these linking variables are required for billing, they should be present for all Medicare FFS patients, and are, therefore, ideally suited to support merging claims and EHR data. However, hospitals will meet Hospital IQR Program requirements if they submit linking variables on 95 percent or more of discharges with a Medicare FFS claim for the same hospitalization during the measurement period.

(10) Public Reporting

(a) Voluntary Reporting Period

We will not publicly report data collected during the voluntary reporting period. Hospitals that submit data for this measure during the voluntary reporting period will receive confidential hospital-specific reports that detail submission results from the applicable reporting period, as well as the Hybrid HWM measure results assessed from merged files created by our merging of the EHR data elements submitted by each participating hospital with claims data from the same set of index admissions. Hospitals voluntarily reporting will receive information and instructions on the use of the electronic specifications for this measure, have an opportunity to test extraction and submission of data to CMS, and receive feedback reports from CMS, available via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System), with details on the success.

(b) Mandatory Reporting

We proposed mandatory data submission, including public reporting of the Hybrid HWM measure, beginning with the data from the July 1, 2023 through June 30, 2024 reporting period, affecting the FY 2026 payment determination and for subsequent years. We anticipate this data will be included in the July 2025 refresh of the *Care Compare* website or its successor website.

The EHR data will be merged with the associated claims data, and then Hybrid HWM measure results will be shared with hospitals in the confidential hospital-specific feedback reports planned for the spring of 2025, providing hospitals a 30-day review period prior to public reporting. Thereafter, in subsequent reporting years, we will follow a similar operational timeline for EHR data submissions, availability of hospital specific reports, and public reporting on the *Care Compare website* or its successor website.

We refer readers to section IX.C.9.f. of the preamble of this final rule for more details and proposals related to data submission requirements for hybrid measures, including the Hybrid HWM measure.

We invited public comment on this proposal.

Comment: Many commenters supported adoption of the Hybrid HWM measure into the Hospital IQR Program. Some commenters noted their appreciation of the benefits of the Hybrid HWM measure, such as providing a more comprehensive picture of mortality rates than the condition-specific mortality measures, and, particularly for low-volume hospitals not captured by condition-specific mortality measures, providing information on the effects of COVID–19 on 30-day mortality nationally.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern regarding the administrative burden of reporting the Hybrid HWM measure and recommended ways to minimize the burden of submitting the data. Specifically, commenters recommended completely aligning the data requirements for the two hybrid measures (Hybrid HWM and Hybrid HWR), and suggested that hospitals should be able to submit the CCDE and linking variables needed for both measures in a single submission, such as through a single QRDA file such as is currently used to submit eCQMs.

Response: We thank the commenters for their recommendations on reducing the administrative burden of the Hybrid HWM measure. We note that we aligned the specifications and data requirements for the two hybrid measures as much as possible, with the Hybrid HWM measure adding only one additional CCDE. We clarify that we intend to allow hospitals to submit a patient's CCDE and linking variables for both measures using a single submission to further minimize provider burden related to reporting of these measures.

Comment: Several commenters recommended modifications to the Hybrid HWM measure cohort and exclusion criteria. Some commenters expressed support for the current exclusion criteria as appropriately excluding patients for whom hospitals have limited ability to prevent death. A few commenters suggested that the exclusion criteria be expanded and that the specifications be updated to more adequately address patient preferences

regarding life support treatments. Additionally, several commenters requested clarification on and further justification for the age range of patients included in the Hybrid HWM measure cohort as well as any differences between this measure and the Hybrid HWR measure cohort.

Response: We appreciate the commenters' feedback. We believe that the mortality measure should only include patients for whom hospitals can meaningfully influence survival and we believe the measure, as currently specified, achieves this objective. As proposed, in addition to the exclusions for hospice and cancer, the measure specifications also exclude patients with numerous principal or secondary discharge diagnoses POA for conditions for which hospitals have limited ability to influence survival, and therefore, death would not be a quality signal.[949] These conditions were selected with independent clinical expert input. For more details, we refer readers to the measure Data Dictionary and particularly the Survival NonInclusion tab available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. While we agree patient preferences regarding life support and ''do not resuscitate'' (DNR) orders are important to consider, they are currently differentially reported by hospitals, making them unreliable at this time for risk adjustment. CMS will continue to monitor coding patterns around these codes.

We note that the age ranges do differ between the Hybrid HWM measure and the Hybrid HWR measure. The Hybrid HWR measure includes all FFS beneficiaries 65 and older who meet the rest of the cohort criteria. For the Hybrid HWM measure, patients over the age of 94 are not included to avoid holding hospitals responsible for the survival of the oldest elderly patients, who may be less likely to have survival as a primary goal. We refer readers to the measure specifications for both measures available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: A number of commenters requested additional information regarding the data requirements for the Hybrid HWM measure. Specifically, a commenter requested clarification on the percentage of admissions requiring inclusion of lab results for the Hybrid HWM measure versus the Hybrid HWR measure. Several commenters specifically asked for the public posting of the measure methodology so hospitals and vendors can begin to familiarize themselves with it.

Response: We thank the commenters for their input. For the Hybrid HWM measure, hospitals are required to report vital signs for 90 percent or more of the hospital admissions for Medicare FFS patients, aged between 65 and 94 years old discharged in the measurement period, and laboratory test results for 90 percent or more of hospital admissions for nonsurgical patients, meaning those not included in the surgical divisions of the Hybrid HWM measure. For the Hybrid HWR measure, hospitals are required to report vital signs for 90 percent or more of the hospital discharges for Medicare FFS patients, aged 65 years or older (no upper age limit) in the measurement period (as determined from the claims submitted to CMS for admissions that ended during the same reporting period); and submit laboratory test results for 90 percent or more of discharges for nonsurgical patients, meaning those not included in the surgical specialty cohort of the Hybrid HWR measure. Additional information on the specifications of the Hybrid HWM measure can be found on the eCQI resource center website at: *https://ecqi.healthit.gov/eh-cah?qt-tabs_eh=3&globalyearfilter=2022* and for the Hybrid HWR measure also on the QualityNet website: *https://qualitynet.cms.gov/inpatient/measures/hybrid/resources*.

Comment: Several commenters supported the inclusion of data from the EHR to improve risk adjustment and measure validity. Commenters noted the benefits of risk adjustment include an increased likelihood of fair comparisons of provider performance and recognition of social determinants of health. However, several commenters felt the current risk adjustment approach was insufficient in preventing disproportionate penalties for safety-net providers and academic medical centers that treat greater proportions of vulnerable patients, urged CMS to conduct additional social risk factor testing approaches such as multi-level models or testing social factors prior to clinical variables, and recommended adjustment for social determinants of health. A commenter recommended CMS test the feasibility of using non-clinical EHR-derived data elements to inform development of a risk adjustment approach for social risk factors. Additionally, several commenters recommended the following additional risk factors be added to the measure: ''code status'', which the commenter expressed is strongly associated with mortality, particularly at the facility level, pre- and post-admission functional and cognitive status, and lactate and procalcitonin as indicators of disease severity. A commenter also expressed support for the inclusion of EHR data and suggested the need for oversight of the data entry process to ensure reliable data.

Response: We thank the commenters for their support of moving toward more digital measurement and inclusion of EHR data to improve risk adjustment. With regards to the inclusion of social risk factors, our analysis of the fully aligned claims-only version of the HWM measure using data from July 1, 2016–June 30, 2017 found that adding risk variables into the multivariate model again attenuates the effect size for most divisions (the odds ratios for most divisions are close to 1 in the multivariate model), with the exception of the surgical cancer division that comprises only 2 percent of the cohort.[950] Furthermore, we found that adjusting for either social risk factor had little impact on measure scores; measure scores calculated with and without social risk factors were highly correlated. We continue to be committed to better understanding the relationships between social risk factors, patient outcomes, and quality of care. We refer readers to section IX.B. of this final rule for more information regarding CMS' efforts to measure and improve health equity.

With regards to the specific clinical risk adjustment factors included in the Hybrid HWM measure, we believe the risk adjustment approach is adequate for accounting for case mix and service mix. Risk model testing using data from July 1, 2016–June 30, 2017 showed good model discrimination, predictive ability, and model fit.[951] We approached risk variable selection from the perspective

[949] Glennon G, Triche E, Wang Y, et al. Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Methodology Report Version 2.0. March 2020. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

[950] National Quality Forum. Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure (NQF #3504) and Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure. NQF #3502. Available at *https://www.qualityforum.org/Qps/QpsTool.aspx*.

[951] Glennon G, Triche E, Wang Y, et al. Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Methodology Report Version 2.0. March 2020. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

of ensuring a parsimonious list of clinical EHR variables that would minimize hospital burden to report the data and provide face validity from a clinical perspective. As candidate risk variables, the CCDE are consistently captured, captured with a standard definition, and entered into the electronic health record in a structured field and can be feasibly extracted, as shown during development and testing, and subsequently presented to NQF. We will continue to evaluate the risk adjustment approach and specific risk factors, including those recommended by commenters such as code status, cognitive and functional status, and disease severity indicators, during regular measure maintenance as additional CCDE are better captured in the EHR and meet these guiding principles.

With regards to data entry oversight, the data elements included in the risk model represent clinical data used in the provision of clinical care. They were selected due to their regular occurrence within usual clinical workflow as well as their standardization, reproducibility, and ability to be validly extracted from the EHR; therefore, we are confident in the ability of facilities to reliably report this data.

Comment: Several commenters did not support the adoption of the Hybrid HWM measure. A few commenters questioned the validity of the Hybrid HWM measure and requested a more robust face validity assessment and an analysis of the correlation of the HWM measure with the HWR measure. The commenters felt there was insufficient evidence to support a hospital-wide mortality outcome or to demonstrate that hospitals can directly or indirectly impact mortality rates within 30 days of an inpatient admission via a process, intervention, or service that could be attributed to an individual hospital. Several commenters felt the condition-specific mortality measures already in use in CMS programs were sufficient and/or more actionable than a hospital-wide measure, and adding a hospital-wide mortality measure meant a single mortality event could count against a hospital across more than one measure. A few commenters recommended that we adapt the condition-specific measures into hybrid measures to eventually replace the Hybrid HWM in the Hospital IQR Program. Additionally, several commenters questioned the usefulness of the Hybrid HWM measure to hospitals and patients given the limited variation in performance scores and perceived limits in hospitals' ability to understand and improve quality based upon claims data.

Response: We thank the commenters for their input. The Hybrid HWM measure was NQF endorsed in June 2019 following review by the NQF Scientific Methods Panel and recommendation for endorsement by the Patient Safety Standing Committee.[952] The face validity and empiric validity testing results submitted to NQF for measure endorsement support the validity of the Hybrid HWM measure. In terms of face validity, 5 of 6 respondents (83 percent) to the Technical Expert Panel (TEP) survey indicated that they somewhat, moderately, or strongly agreed, with the following statement: ''The risk-standardized hospital visits rates obtained from the Hybrid HWM measure, as specified, can be used to distinguish between better and worse quality facilities.'' Empiric validity testing, performed in the claims-based hospital-wide mortality measure that is identical to the Hybrid measure except for the addition of the CCDE in the Hybrid version, demonstrates a relationship between Hospital Wide Mortality and nurse-to-bed ratio, as well as to the condition-specific mortality rates in the Overall Hospital Quality Star Rating Mortality Group Score.

In terms of variation, while we recognize that many hospitals may be categorized as ''no different than the national average'', the variation in performance (submitted to NQF based on data from July 1, 2016–June 30, 2017) between the hospitals with the lowest mortality rates (risk-standardized mortality rate or RSMR of 3.95 percent) and the hospitals with the highest mortality rate (RSMR of 8.7 percent) shows there is a clear quality gap. Specifically, the best performing hospital (RSMR of 3.95 percent) is performing 43 percent better than an average performer (or has about 30 fewer deaths per 1000 patients compared to the average performer), while the worst performing hospital (8.70 percent) is performing 25 percent worse than an average performer (or has 18 more deaths per 1000 patients). We believe this information is important for hospitals to understand and improve their quality and for patient decision-making.

We agree that the condition- and procedure-specific mortality measures provide valuable information to many hospitals to focus their quality improvement efforts. We interpret the commenters to be referring to the condition-specific mortality measures in the Hospital VBP Program (Pneumonia (PN) 30-Day Mortality Rate (Updated Cohort) (76 FR 26495 through 26511); Heart Failure (HF) 30-Day Mortality Rate (76 FR 26495 through 26511); Coronary Artery Bypass Grafting (CABG) 30-Day Mortality Rate (81 FR 56996 through 56998); Chronic Obstructive Pulmonary Disease (COPD) 30-Day Mortality Rate (80 FR 49557 through 49558); and Acute Myocardial Infarction (AMI) 30-Day Mortality Rate (76 FR 26495)). We encourage hospitals to consider their results on those measures together with their Hybrid HWM measure results and the individual service line results within the Hybrid HWM. We also note that the Hybrid HWM measure offers the additional advantage of measuring mortality rates in smaller volume hospitals and provides an important balancing measure for CMS' existing Hybrid HWR measure.

Comment: Many commenters supported the proposal to conduct a voluntary reporting period for the Hybrid HWM measure prior to mandatory reporting, to allow hospitals time to gain familiarity with the measure and submission process. Several commenters suggested that during the voluntary reporting period, we monitor closely for unintended consequences and also evaluate and make public any issues with EHR data extraction or submission and measure validity. Several commenters felt it was premature to adopt mandatory reporting of the Hybrid HWM measure and recommended CMS implement an additional voluntary reporting period or delay mandatory reporting by an additional year, citing concerns such as hospital and vendor readiness, the capabilities of the QualityNet system to receive the large amount of data that would be submitted, the need to consider additional risk adjustment once data are collected through voluntary reporting, and confirmation of the benefit of the added effort of hybrid measure reporting.

Response: We agree with commenters that a voluntary reporting period will allow hospitals time to gain experience with submitting the Hybrid HWM measure, and we believe one voluntary reporting period will be sufficient. We disagree that it is premature to implement mandatory reporting of the measure the following year, noting the mandatory reporting does not begin until FY 2026 payment determination (data period July 1, 2023 through June 30, 2024). The Hybrid HWM measure is closely aligned with the Hybrid HWR measure which utilizes nine of the ten CCDEs required for the Hybrid HWM

[952] National Quality Forum, Consensus Standards Approval Committee Web Meetings: Fall 2019 Meeting Summary. *https://www.qualityforum.org/About_NQF/CSAC/Meetings/2019_CSAC_Meetings.aspx*.

measure. One hundred and forty-nine hospitals have already successfully participated in the first voluntary reporting period for the Hybrid HWR, and therefore, we are confident that hospitals can continue to improve their data collection and submission systems throughout the second Hybrid HWR and the Hybrid HWM voluntary reporting periods. With regards to data submission to the CMS Hospital Quality Reporting (HQR) system (formerly referred to as the QualityNet system or QualityNet Secure Portal), we believe CMS systems are fully capable of receiving all the required data files. We are committed to continuing to improve these systems and responding to stakeholder feedback during voluntary and mandatory reporting.

Comment: A few commenters requested that CMS seek stakeholder feedback on options for how the measure will be publicly reported.

Response: We appreciate commenters' suggestion. In the FY 2022 IPPS/LTCH PPS proposed rule, where we proposed this measure, we solicited comments on all aspects of this measure, including public reporting, but did not receive any specific suggestions on how the measure data would be publicly reported. We also generally encourage stakeholders to submit such comments via rulemaking or through our outreach and education efforts, such as through webinars, national provider calls, stakeholder listening sessions, as well as through other collaborative engagements with stakeholders.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

c. Adoption of the COVID–19 Vaccination Coverage Among HCP Measure Beginning With Shortened Reporting Period From October 1, 2021 Through December 31, 2021, Affecting the CY 2021 Reporting Period/FY 2023 Payment Determination, and for Subsequent Years

(1) Background

On January 31, 2020, the Secretary of the U.S. Department Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[953] COVID–19 is a contagious respiratory infection[954] that can cause serious illness and death. Older individuals and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[955]

As stated in the proposed rule, as of April 2, 2021 the U.S. reported over 30 million cases of COVID–19 and over 550,000 COVID–19 deaths.[956] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[957] From December 2, 2020 through January 30, 2021, more than 100,000 Americans were in the hospital with COVID–19 at the same time.[958] As of July 21, 2021, the U.S. has reported over 34 million cases of COVID–19 and over 607,000 COVID–19 deaths.[959]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[960] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[961] Thus, the Centers for Disease Control and Prevention advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[962] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface.[963] Subsequent to the publication of the proposed rule, the CDC has confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[964] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[965] Although infections through inhalation at distances greater than six feet from an infectious source are less likely than at closer distances, the phenomenon has been repeatedly documented under certain preventable circumstances. These transmission events have involved the presence of an infectious person exhaling virus indoors for an extended time (more than 15 minutes and in some cases hours) leading to virus concentrations in the air space sufficient to transmit infections to people more than 6 feet away, and in some cases to people who have passed through that space soon after the infectious person left. Personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, but COVID–19 can still spread between health care personnel (HCP) and patients, or from patient to patient given the close contact that may occur during the provision of care.[966] The CDC has emphasized that health

[953] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[954] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[955] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[956] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[957] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895*. Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html*.

[958] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized*.

[959] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[960] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[961] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[962] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[963] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[964] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[965] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html*.

[966] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission*.

care settings, including long-term care settings, can be high-risk places for COVID–19 exposure and transmission.[967]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately helps restore societal functioning.[968] On December 11, 2020, the FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[969] Subsequently, FDA issued EUAs for additional COVID–19 vaccines.[970]

FDA determined that the vaccines met the statutory criteria for issuance of an EUA. The totality of the available data provided clear evidence that the vaccines may be effective to prevent COVID–19, and that the known and potential benefits of the vaccines, when used as authorized to prevent COVID–19, outweighed the known and potential risks.[971]

As part of its national strategy to address COVID–19, the Biden Administration stated on March 25, 2021 that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[972] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including HCP providing direct care to patients with COVID–19, and individuals at highest risk for developing severe illness from COVID–19.[973] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccine given the potential for transmission in health care settings and the need to preserve health care system capacity.[974] Research suggests most states followed this recommendation,[975] and HCP began receiving the vaccine in mid-December of 2020.[976]

Frontline healthcare workers, such as those employed in acute care hospitals, are being prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the United States.[977] As of July 2, 2021, the CDC reported that over 328 million doses of the COVID–19 vaccine had been administered, and approximately 155.9 million people had received a complete vaccination course.[978] Subsequent to the publication of the proposed rule, on June 3, 2021 the White House confirmed that there was sufficient vaccine supply for all Americans.[979]

We believe it is important to incentivize and track HCP vaccination in acute care facilities through quality measurement to protect health care workers, patients, and caregivers, and to help sustain the ability of hospitals to continue serving their communities throughout the PHE and beyond. Therefore, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25571 through 25575) we proposed to adopt a new measure, COVID–19 Vaccination Coverage Among HCP, beginning with a shortened reporting period from October 2021 through December 2021. The CY 2021 Reporting Period for the FY 2023 Payment Determination is shorter than the reporting period we proposed for subsequent years to expedite data collection of this measure in response to the current PHE. The measure will assess the proportion of a hospital's health care workforce that has been vaccinated against COVID–19.

Although at this time data to show the effectiveness of COVID–19 vaccines to prevent asymptomatic infection or transmission of SARS–CoV–2 are limited, we believe hospitals should track the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[980] Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[981] and we believe HCP

[967] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[968] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[969] U.S. Food and Drug Administration. (2021). Pfizer-BioNTech COVID–19 Vaccine. Available at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine*.

[970] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download*; U.S. Food and Drug Administration. (2020). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download*; U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download*.

[971] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. *Available* at *https://www.fda.gov/media/144412/download* Tech COVID–19 Vaccine EUA Letter of Authorization (*fda.gov*); U.S. Food and Drug Administration. (2020). ModernaTx, Inc. COVID–19 Vaccine EUA Letter of Authorization. *Available* at: *https://www.fda.gov/media/144636/download*; U.S. Food and Drug Administration. (January 2020). Guidance Document: Emergency Use Authorization of Medical Products and Related Authorities. Accessed on December 17, 2020, at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#scope*.

[972] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. March 29, 2021. Accessed at *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/*.

[973] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[974] Dooling, K, McClung, M, and et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[975] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/*.

[976] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f*.

[977] CDC/The National Institute for Occupational Safety and Health (NIOSH). Health Care Workers. Accessed on February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html#:~:text=HEALTHCARE%20WORKERS,-Related%20Pages&text=Healthcare%20is%20the%20fastest%2Dgrowing,of%20the%20healthcare%20work%20force*.

[978] This information has been updated from the proposed rule to reflect current data from the CDC. COVID Data Tracker. COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations*.

[979] Press Briefing by White House COVID–19 Response Team and Public Health Officials | The White House. Accessed on July 21, 2021 at *https://www.whitehouse.gov/briefing-room/press-briefings/2021/06/03/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-40/*.

[980] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*.

[981] Measure Applications Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

COVID–19 vaccination in hospitals could similarly increase uptake among that patient population.

We also believe that publishing the HCP vaccination rates will be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in facilities such as acute care facilities.

(a) Measure Specifications

The denominator is the number of HCP eligible to work in the healthcare facility for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[982]

The numerator is the cumulative number of HCP eligible to work in the health care facility for at least one day during the reporting period and who received a completed vaccination course against COVID–19 since the date the vaccine was first available or on a repeated interval if revaccination is recommended.[983] Vaccination coverage for the purposes of this measure is defined as the estimated percentage of HCP eligible to work at acute care hospitals for at least one day who received a completed vaccination course.[984] A completed vaccination course may require one or more doses depending on the EUA for the specific vaccine used. We refer readers to *https://www.cdc.gov/nhsn/nqf/index.html* for more details on the measure specifications.

(b) Review by the Measure Applications Partnership (MAP)

The COVID–19 Vaccination Coverage Among HCP measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List), a list of measures under consideration for use in various Medicare programs.[985] When the MAP Hospital Workgroup convened on January 11, 2021, it reviewed the measures on the MUC List, including the COVID–19 Vaccination Coverage Among HCP measure. [986] The MAP recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the Hospital IQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[987] The MAP also stated that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to facilities will allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing rates of COVID–19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[988]

In its preliminary review, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[989] To mitigate its concerns, the MAP Hospital Workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[990] Subsequently, the MAP Coordinating Committee met on January 25, 2021, to review and make a recommendation on the COVID–19 Vaccination Coverage Among HCP measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications are further refined specifically saying that ''the incomplete specifications require immediate mitigation and further development should continue.''[991] In its final report, the MAP noted that the measure would add value to the program measure set by providing visibility into an important intervention to limit COVID–19 infections in healthcare personnel and the patients for whom they provide care.[992] The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.[993]

In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with MAP Coordinating committee on March 15, 2021. CMS and the CDC provided additional information to the MAP Coordinating Committee at that meeting to address vaccine availability, the alignment of the COVID–19 Vaccination Coverage Among HCP measure as closely as possible with the Influenza HCP vaccination measure (NQF #0431) specifications, and the definition of HCP used in the measure. At this meeting, CMS and the CDC also presented preliminary findings from the testing of the numerator of COVID–19 Vaccination Coverage Among HCP, which is currently in process. These preliminary findings showed that the numerator data should be feasible and reliable. Testing of the numerator of the number of healthcare personnel vaccinated involves a comparison vaccination data collected by the CDC directly from long-term care facilities (LTCFs) through NHSN with vaccination data independently reported to the CDC through the Federal pharmacy

[982] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications.*

[983] Measure Applications Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[984] We note that in the FY 2022 IPPS/LTCH PPS proposed rule, in this sentence, we inadvertently referred to ''IPFs'' instead of acute care hospitals (86 FR 25573).

[985] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 12, 2021.

[986] The MUC List and the MAP referred to the measure as the ''SARS–CoV–2 Vaccination Coverage Among Healthcare Personnel.''

[987] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[988] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[989] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[990] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[991] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[992] Measure Applications Partnership. 2020–2021 Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on March 12, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020–2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC–LTC.aspx.*

[993] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 18 at: NQF: Measure Applications Partnership (qualityforum.org).

partnership program for delivering vaccination to LTC facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination from December 2020 to January 2021, the number of healthcare workers vaccinated in approximately 1,200 facilities, which had data from both systems the number of healthcare personnel vaccinated, was highly correlated between these 2 systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[994] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe this data indicates the measure is feasible and reliable for use in the Hospital IQR Program.

We value the recommendations of the MAP and considered these recommendations carefully. Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on vulnerable populations. CMS continues to engage with the MAP to mitigate concerns and appreciates the MAP's conditional support for the measure.

(3) NQF Endorsement

Under section 1886(s)(4)(D)(i) of the Act, unless the exception of subclause (ii) applies, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. Section 1886(s)(4)(D)(ii) of the Act provides an exception to the requirement for NQF endorsement of measures: in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

This measure is not NQF-endorsed and has not been submitted to NQF for endorsement consideration. The CDC, in collaboration with CMS, is planning to submit the measure for consideration in the NQF Fall 2021 measure cycle.

Because this measure is not NQF-endorsed, we considered other available measures. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP, therefore we believe the exception in section 1186(s)(4)(D)(ii) of the Act applies.

(4) Data Submission and Reporting

Given the time-sensitive nature of this measure in light of the PHE, we proposed that for the FY 2023 program year, the reporting period would be from October 1, 2021 through December 31, 2021. The reporting period we proposed is shorter than the reporting period for subsequent years to expedite data collection for this measure in order to respond to the current PHE. Thereafter, we proposed quarterly reporting deadlines for the Hospital IQR Program beginning with the CY 2022 reporting period/FY 2024 payment determination and for subsequent years.

To report this measure, we proposed that hospitals would collect the numerator and denominator for the COVID–19 Vaccination Coverage Among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet Hospital IQR Program requirements. While we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that hospitals would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a hospital's healthcare personnel while balancing the costs of reporting. If a hospital submits more than one week of data in a month, the most recent week's data will be used to calculate the measure. For example, if first and third week data are submitted, third week data will be used. If first, second, and fourth week data are submitted, fourth week data will be used. Each quarter, the CDC will calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital, which will be calculated by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. CMS will publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

As described in section IX.C.9.j., hospitals will report the number of HCP eligible to have worked at the facility during the self-selected week that the hospital reports data for in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week.

We invited public comment on this proposal.

Comment: Many commenters supported our proposal to adopt the COVID–19 Vaccination Coverage Among HCP Measure. Commenters acknowledged that evidence confirms vaccination of HCP effectively reduces infection, and consumers deserve information on vaccination coverage among HCP when choosing where to receive care. Some commenters noted that the entire health care team, not just physicians, have daily contact with patients and measuring vaccination status of all HCP protects both patients and staff.

Response: We thank commenters for their support of the measure and agree that vaccination remains important as the PHE continues.

Comment: Many commenters noted that, presently, all COVID–19 vaccines are authorized through an EUA. Some of these commenters expressed that individuals remain hesitant to receive vaccination during the EUA and the measure is premature until such time that a vaccine has received full FDA approval. A few commenters stated that these vaccines have been available and deployed for a short amount of time and there is not currently sufficient information available to include a vaccination measure in quality reporting programs. Several commenters worried that the country lacks experience with these vaccines, and the measure proposal is premature. Several commenters asserted that, until vaccines receive full FDA approval, CMS lacks the information necessary to include this measure in the Hospital IQR Program. A few commenters believed that the measure should be endorsed by the National Quality Forum (NQF) before it is adopted in the program. A few commenters recommended a delay indefinitely until vaccines receive full FDA approval or NQF endorsement.

Response: While we support widespread vaccination coverage, we also understand that some HCP may be concerned about receiving the COVID–19 vaccine prior to the vaccine receiving full FDA approval. We refer readers to

[994] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

the FDA website for additional information related to FDA's process for evaluating an Emergency Use Authorization (EUA) request at *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained*. While we recognize there are differences between EUA authorization and full FDA approval, we note that the process for each is scientifically rigorous. Each vaccine manufacturer that received EUA authorization enrolled tens of thousands of participants in randomized clinical trials, which is similar to what is required for full FDA approval.[995] Manufacturers submit the same robust and rigorous data for both an EUA authorization and full FDA approval, and more than 330 million doses of COVID–19 vaccines authorized by EUAs have been administered.[996] We believe these vaccines to be proven safe and effective.

We further emphasize that the COVID–19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates, not an outcome measure for which hospitals are held directly accountable for a particular outcome, and does not require HCP to receive the vaccination. We believe that given the current COVID–19 PHE and the need for continued monitoring and surveillance following the PHE, it is important to adopt this measure as quickly as possible to allow tracking and reporting of the COVID–19 Vaccination Coverage Among HCP measure. This tracking would allow hospitals to identify the appropriateness and effectiveness of their initiatives to improve vaccination coverage and would provide consumers with important information.

Because of this, we believe it is appropriate to use the exception provided in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act. That exception allows for, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We note that there is no NQF endorsed measure on the topic of COVID–19 vaccination coverage among healthcare personnel, but the CDC, in collaboration with CMS, is planning to submit the measure for consideration in the NQF 2021 measure cycle. The intent of adopting the COVID–19 Vaccination Coverage Among HCP measure is to collect and report data that will support public health tracking and provide patients, beneficiaries, and their caregivers with important information to support informed decision making. For these reasons, we believe that it is appropriate to collect and report these data as soon as possible.

Comment: Some commenters requested that, given the relatively new roll-out of COVID–19 vaccination, CMS work with the CDC to continue to refine the measure as new evidence comes forward about vaccination during the PHE. A few commenters encouraged CMS to continue to update the measure as new evidence on COVID–19 continues to arise.

Response: We thank the commenters for their suggestions. We will continue to work closely with the CDC and will consider any updates to the measure in future rulemaking as appropriate.

Comment: Several commenters expressed concern that the future potential for booster vaccines is unknown and asserted it is premature to adopt the measure before this information is available. Some commenters requested clarification as to how the measure may change should boosters be needed. Several commenters stated that, while CMS aims to closely align the measure with the Influenza Vaccination Coverage Among HCP (NQF #0431) measure, the measures differ as the flu is seasonal in nature and requires a single vaccine while multiple doses or boosters may be required for COVID–19 as the evidence for appropriate vaccination course is determined over time.

Response: We thank the commenters for their feedback. With regard to commenters stating that it is premature to adopt the measure, we believe that COVID–19 vaccines are a crucial tool for slowing the spread of disease and death among residents, staff, and the general public. Based on the FDA's review, evaluation of the data, and its decision to authorize three vaccines for emergency use, these vaccines meet FDA's standards for an EUA for safety and effectiveness to prevent COVID–19 disease and related serious outcomes, including hospitalization and death.[997] The combination of vaccination, universal source control (wearing masks), social distancing, and handwashing offers further protection from COVID–19.[998] Since the publication of the proposed rule, the emergence of coronavirus variants have resulted in an 84% increase in new virus cases. Given the EUA decisions by the FDA and the continued PHE, we disagree that adoption of the measure is premature, and believe our proposal to add the COVID–19 Vaccination Coverage among HCP measure to the Hospital IQR Program is appropriate and necessary for patient safety.

We appreciate commenter's concerns about the potential need for boosters. The COVID–19 Vaccination Coverage Among HCP measure is a measure of a completed vaccination course (as defined in section IX.C.9.c.(2).(a). of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25573)) and does not address booster shots. Currently, the need for COVID–19 booster doses has not been established, and no additional doses are currently recommended for HCP.[999] We do not have enough information to comment on the details of the booster vaccination or the associated data collection. However, we believe that the numerator is sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' and therefore the measure is sufficiently specified to address boosters.

Comment: Some commenters expressed concern that the COVID–19 Vaccination Coverage Among HCP measure is intended to align with the Influenza Vaccination Coverage Among HCP (NQF #0431) measure but asserted that the measure specifications for COVID–19 vaccination are more complex than those for influenza vaccination, noting that the Influenza Vaccination Coverage Among HCP (NQF #0431) measure does not have to address full versus partial vaccination status (and whether and how to account for partial vaccination), the potential need for boosters, or the approval status of vaccines.

[995] Harvard Law Petrie-Flom Center. ''What's the Difference Between Vaccine Approval (BLA) and Authorization (EUA)?'' June 15, 2021. Available at: *https://blog.petrieflom.law.harvard.edu/2021/06/15/whats-the-difference-between-vaccine-approval-bla-and-authorization-eua/*.

[996] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker: COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations (Accessed on July 19, 2021).*

[997] U.S. Food and Drug Administration. COVID–19 Vaccines. (2021). Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines*.

[998] Centers for Disease Control and Prevention. Guidance for Unvaccinated People: How to Protect Yourself & Others. June 11, 2021. Available at *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html*. Accessed June 24, 2021.

[999] Centers for Disease Control and Prevention. Vaccine Administration. Available at *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html*. Accessed June 25, 2021.

Response: We acknowledge that while the CDC has sought to align this measure with the Influenza Vaccination Coverage Among HCP measure (NQF #0431),[1000] these are different public health initiatives, and different vaccines, and therefore the measure specifications are not in complete alignment. As the commenter has noted, the reporting requirements for the numerator of the COVID–19 Vaccination Coverage Among HCP measure are due to the fact that some COVID–19 vaccines require two doses to reach full vaccination status, while some COVID–19 vaccines require only one dose. The measures are aligned with respect to the reporting mechanism used to report data (the NHSN) and key components of the measure specifications (for example, the definition of the denominator), but the measures allow for important differences to reflect the reality that the circumstances around vaccine administration (that the commenter points out) are not identical.

Comment: Several commenters opposed any requirement for HCP to receive vaccines. A few commenters noted that HCP may have legitimate reasons to decline vaccination, including contraindications, and should not be required to receive vaccination as a condition of continued employment. Some commenters encouraged CMS to consider vaccination exclusions other than medical contraindications, including for pregnancy or immunocompromised individuals, until there are more data available on vaccination for those individuals. A commenter noted that indications and contraindications have changed throughout the PHE and may necessarily continue to change based on ongoing research. The commenter stated that hospital human resources databases and records cannot accurately capture individuals who decline the vaccine or the reason for the declination, which may impact accuracy of reporting. Several commenters asserted that factors outside of their control, including regional differences in vaccination rates, could put hospitals in those areas at a disadvantage.

Response: We agree with the commenters who note that HCP may have legitimate reasons to decline vaccination, including a contraindication, and this measure does not require HCP to receive the vaccine. The intent of adopting the COVID–19 Vaccination Coverage Among HCP measure is to collect and report data that will support public health tracking and provide patients, beneficiaries, and their caregivers important information to support informed decision making. For these reasons, we believe that it is appropriate to collect and report these data as soon as possible.

As noted in the measure specifications,[1001] HCP who are determined to have a medical contraindication specified by FDA labeling or authorization, CDC, or ACIP recommendations are excluded from the denominator of this measure. The CDC and FDA consider contraindications to vaccination with COVID–19 vaccines to be: (1) Severe allergic reaction (for example, anaphylaxis) after a previous dose or to a component of the COVID–19 vaccine; or (2) immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.[1002] For example, as stated in the FDA-authorized Fact Sheets for two COVID–19 vaccines, ''the decision to administer the [Pfizer/Moderna] COVID–19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances.'' [1003] We also recognize that there are reasons, including religious objections or concerns regarding an individual provider's specific health status, that may lead individual HCP to decline vaccination. We emphasize that this measure does not mandate vaccines, it only requires reporting of vaccination rates for successful program participation. We do not expect 100 percent vaccination coverage among HCP. However, we do believe that coverage rates are meaningful data for patients and beneficiaries to use in choosing a hospital, and can also be used for public health tracking.

Comment: Other commenters noted that vaccine mandates may push HCP to leave their jobs. Some commenters stated that vaccination has become a political flashpoint and mandates could drive further vaccine hesitancy. A few commenters noted that, if the health care system moves to mandate vaccination, it would be redundant to any employer or State-level vaccine requirements. A few commenters expressed concerns about the potential impact of State legislation or regulation that may limit or prohibit employers from requiring vaccination or requesting vaccine status from HCP.

Response: We reiterate that the COVID–19 Vaccination Coverage Among HCP measure does not require or mandate HCP to receive the vaccination, it only requires reporting of vaccination rates for successful program participation. We believe that the unprecedented risks associated with the COVID–19 PHE warrant direct attention, especially because HCP are working directly with and in close proximity to patients. To support a comprehensive vaccine administration strategy, we encourage hospitals to voluntarily engage in the provision of appropriate and accessible education and vaccine-offering activities. Many hospitals across the country are educating staff, patients, and patient representatives, participating in vaccine distribution programs, and voluntarily reporting vaccine administration. The CDC has a number of resources [1004] available to providers to assist in building vaccine confidence. CMS also has a web page to help providers, including hospitals, find resources related to the COVID–19 vaccines.[1005] There are a number of toolkits and videos providers can use to stay informed and to educate their employees, patients and communities about the COVID–19 vaccines.

With regard to concerns about state-level legislation that may limit a hospital's ability to require vaccination or request vaccine status from HCP, we reiterate that the COVID–19 Vaccination Coverage Among HCP measure does not require HCP to receive the vaccination and is a process measure that assesses HCP vaccination coverage rates, not an outcome measure for which hospitals are held directly accountable for a particular outcome. While we are aware

[1000] Measure Applications Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1001] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[1002] Centers for Disease Control and Prevention. Contraindications and Precautions. Available at: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications*; Food and Drug Administration. COVID–19 Vaccines. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.*

[1003] Food and Drug Administration. Pfizer-BioNTech COVID–19 Vaccine. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine#additional*; Food and Drug Administration. Moderna COVID–19 Vaccine. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine.*

[1004] Centers for Disease Control and Prevention. Building Confidence in COVID–19 Vaccines. Available at *https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html.*

[1005] Centers for Medicare and Medicaid Services. Coronavirus (COVID–19) Partner Resources. Available at: *https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-resources.*

that at least one state has enacted legislation that prohibits employers from requiring employees to disclose immunization status,[1006] we are not aware of any state legislation that prohibits employers from requesting voluntary reporting of immunization status. We again note that this measure does not require HCP to receive a COVID–19 vaccine and it does not require HCP to report their vaccination status. Additionally, the Equal Employment Opportunity Commission (EEOC) released updated and expanded technical assistance on May 28, 2021,[1007] stating that Federal equal employment opportunity (EEO) laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations. Therefore, we do not believe that this measure conflicts with any Federal or state-level requirements and believe that it is appropriate to require hospitals to report these data.

Comment: Many commenters expressed concern with the HCP definition and believed it to be too broad. Several commenters asserted that the measure, which defines HCP as all individuals receiving a direct paycheck from the hospital regardless of clinical responsibility or patient contact, will be difficult to accurately capture. A few commenters anticipated challenges of accurately counting HCP who work at multiple hospitals or facilities and requested clarification of how to address those HCPs. A few commenters stated that many hospitals will be unable to include an accurate count of adult students/trainees, volunteers, and contractors in the measure denominator. Some commenters recommended that the definition of HCP be narrowed to apply to only clinicians or direct employees. A commenter suggested that CMS include all HCPs in the denominator, including those with contraindications, along with an explanation in public reporting.

Response: We recognize commenters' concerns regarding reporting burden associated with the specifications of this measure specifically around the definition of HCP. We note that given the highly infectious nature of the COVID–19 virus, we believe it is important to encourage all personnel within the hospital, regardless of patient contact, role, or employment type, to receive the COVID–19 vaccination to prevent outbreaks within the hospital which may affect resource availability and have a negative impact on patient access to care.

We also note that CDC's guidance for entering data requires submission of HCP count at the facility level,[1008] and the measure requires reporting consistent with that guidance. Hospitals should count HCP working in all inpatient or outpatient units that are physically attached to the inpatient site and share the same CCN, regardless of the size or type of unit.[1009] Hospitals should also count HCP working in inpatient and outpatient departments that are affiliated with the specific hospital (such as sharing medical privileges or patients), regardless of distance from the hospital and also share the same CCN.[1010] The decision to include or exclude HCP from the hospital's HCP vaccination counts should be based on whether individuals meet the specified NHSN criteria and are physically working in a location that is considered any part of the on-site hospital that is being monitored.[1011] Additionally, the CDC has provided a number of resources including a tool called the Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel to help hospitals log and track the number of HCP who are vaccinated for COVID–19. Hospitals would enter COVID vaccination data for each HCP in the tracking worksheet, and select a reporting week, and the data to be entered into the NHSN will automatically be calculated on the Reporting Summary.[1012]

With regard to the recommendation that all HCP, including those with contraindications, should be captured in the measure denominator, we highlight that some hospitals may opt to include all eligible HCP in the denominator. We note that the measure specifications as proposed permit hospitals to exclude HCP with contraindications to the vaccine as described by the CDC.[1013] We also note that, similar to the specifications of the Influenza Vaccination Coverage Among HCP (NQF #0431) measure, the COVID–19 Vaccination Coverage Among HCP measure specifications as proposed acknowledge that HCP may have contraindications to vaccination and, as such, may decline vaccination.[1014] We further recognize that hospitals may decide to exclude these HCP from the measure denominator, and the measure specifications as proposed permit such exclusion. The intent of the measure is to capture the vaccination rate within hospitals so that patients have information available on HCP vaccination to inform their health care decisions.

Comment: Many commenters expressed concern that the measure is operationally and logistically burdensome. Several commenters believed that reporting the data for one week each month is overly burdensome. Several commenters stated that HCP are not always vaccinated by their employers, which makes tracking difficult. A few of these commenters noted that many hospitals keep employee electronic health records outside of their facility electronic health record system, which complicates tracking. A few commenters noted that reporting HCP vaccination is especially challenging in States that lack immunization registries. Some commenters noted that HHS already facilitates reporting and suggested that hospitals should be permitted to continue using existing state or Federal resources for reporting.

Response: We appreciate commenters' concerns regarding reporting frequency, however we disagree that the frequency is overly burdensome or that hospitals should report once per quarter instead of one week per month, because we believe that important public health

[1006] Montana House Bill 0702 (enacted May 7, 2021). Bill text available at: *https://leg.mt.gov/bills/2021/billpdf/HB0702.pdf.* Bill status including enactment available at: *http://laws.leg.mt.gov/legprd/LAW0203W$BSRV.ActionQuery?P_SESS=20211&P_BLTP_BILL_TYP_CD=HB&P_BILL_NO=0702&P_BILL_DFT_NO=&P_CHPT_NO=&Z_ACTION=Find&P_ENTY_ID_SEQ2=&P_SBJT_SBJ_CD=&P_ENTY_ID_SEQ=.*

[1007] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.* Accessed June 25, 2021.

[1008] COVID–19 Vaccination Non-LTC Healthcare Personnel TOI (*cdc.gov*).

[1009] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[1010] Ibid.

[1011] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Accessed June 2, 2021 at: *https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf.*

[1012] Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel at *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.*

[1013] Centers for Disease Control and Prevention. Contraindications and Precautions. Available at: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications.*

[1014] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

initiatives outweigh this burden. We proposed that hospitals report at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline. We proposed that for each quarter, the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC. We believe that reporting these data on a frequent interval would increase their value by allowing the CDC to better track these important public health data while also being a valuable quality measure that supports consumer choice and hospital improvement initiatives. Consistent monthly vaccination reporting by hospitals via the NHSN will help patients and their caregivers identify hospitals that have potential issues with vaccine confidence or slow uptake among staff. Implementation of voluntary COVID–19 vaccine education and vaccination programs in hospitals will help protect patients and staff.[1015]

With regard to commenters' concerns about reporting burden, we acknowledge there is burden associated with reporting this measure (see section XII.B.7.f. and section I.K. of Appendix A of this final rule). However, we believe the importance of collecting and reporting data on COVID–19 vaccination coverage among HCP is sufficiently beneficial to outweigh this burden. We do recognize that this measure may lead to duplicative reporting if hospitals voluntarily report COVID–19 HCP vaccination information to other data reporting systems in addition to this measure requirement via the NHSN, and we are collaborating with other HHS agencies, including the CDC to minimize reporting burden to the extent feasible.

Comment: Several commenters opposed the shortened reporting period beginning October 1, 2021 and instead recommended CMS delay reporting until at least CY 2022. A few commenters questioned the value of data reported in CY 2021 that will impact the FY 2023 program year.

Response: We appreciate commenters' concerns about the shortened reporting period. However, we believe that given the current COVID–19 PHE and the need for continued monitoring and surveillance, it is important to adopt this measure as quickly as possible to allow tracking and reporting of COVID–19 HCP vaccination coverage. The commenters are correct that data reported in the first shortened reporting period of CY 2021 will impact the FY 2023 program year. Since the declaration of the PHE, COVID–19 has significantly impacted the healthcare system, and we believe that these effects are likely to continue even after such a time as the PHE for COVID–19 expires. We believe that the measure data reported by hospitals will remain relevant to the Hospital IQR Program in future program years.

Comment: Many commenters expressed concern with beginning to report the measure in October 2021. Some commenters cited operational concerns and noted there is insufficient time for hospitals to prepare for reporting. Several commenters requested that, should the measure be adopted, CMS implement voluntary reporting for the first year. Some commenters suggested that hospitals not be required to report this measure data until January 2022. Other commenters urged CMS to delay reporting until at least October 2022.

Response: We recognize commenters' concerns about operational requirements of reporting. However, we believe that given the current COVID–19 PHE as well as the need for continued monitoring and surveillance, it is important to adopt this measure as quickly as possible to allow tracking and reporting of COVID–19 Vaccination Coverage Among HCP measure. Therefore, we believe it is appropriate to adopt the measure at this time.

Comment: Many commenters opposed public reporting of the COVID–19 Vaccination Coverage Among HCP measure data. Some commenters recommended the measure data should not be publicly reported until the vaccines receive full FDA approval and NQF endorsement. A few commenters noted that, due to the unique nature of the PHE and the relatively limited experience administering vaccines, the measure data should not be publicly reported. A commenter requested that CMS reconsider how the measure is calculated for public reporting. They supported the concept of reporting one quarter of data but noted that, because the measure will provide information for a single point in time, it will quickly become outdated in the rapidly changing COVID–19 landscape, and thus would not be meaningful, nor would it reflect safety or quality of care. They recommend that after the first refresh, rather than calculating a summary measure of the COVID–19 vaccination coverage from the 3 monthly modules of data reported for the quarter during each refresh and adding one additional quarter of data to the measure calculation during each advancing refresh, until the point that four full quarters of data is reached, to use an alternate approach. They recommend updating the information monthly with only the most recent data, such that the measure would be consumed as the most recent quarter of data refreshed quarterly. They caution that averaging over 12 months would result in the dilution of the most recent, and potentially more meaningful information, and may actually discourage higher provider vaccine uptake rates since it would be harder to change performance on this measure. A few commenters worried that publicly reporting the measure data could misrepresent vaccination rates at hospitals and may further drive vaccine hesitancy.

Response: We recognize commenter's concerns about public reporting and understand that a rolling average of data may not accurately represent a hospital's most recent COVID–19 vaccination data as improvements over time could be less apparent given the inclusion of older data. Based on these concerns, and as previously stated, we will not finalize our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data as proposed. As opposed to averaging over four rolling quarters, we will instead update the public reporting to use quarterly reporting to only report the most recent quarter of data, which allows the most recent quarter data to be displayed without combining it with older quarters of data. This would result in information that is more up to date and meaningful and not diluted with older data. We reiterate that this modification of our proposal does not affect the data collection schedule established for submitting data to NHSN for the COVID–19 vaccination measure. This would simply update the data that are displayed for the public reporting purposes.

We also understand that some HCP may be hesitant to receive the COVID–19 vaccine. The intent of adopting the COVID–19 Vaccination Coverage Among HCP measure is to collect and report data that will support public health tracking and provide patients,

[1015] Centers for Disease Control and Prevention. Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID–19 Vaccination. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html.* Accessed June 26, 2021.

beneficiaries, and their caregivers information to support informed decision making. We believe that it is appropriate and important to collect and report these data and to make the data publicly available in light of the public interest.

Comment: A commenter disagreed with data cited from the CDC in the FY 2022 IPPS/LTCH PPS proposed rule on the spread and manner of transmission of COVID–19.

Response: We reiterate our close work with CDC and note that all data on the spread and manner of transmission of COVID–19 cited in the proposed rule came directly from the CDC.[1016]

Comment: A commenter recommended that CMS include reporting of pertussis vaccines in addition to the COVID–19 Vaccination Coverage Among HCP measure.

Response: We thank the commenter for this suggestion.

After consideration of the public comments we received, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021 for the FY 2023 payment determination, and continuing with quarterly reporting deadlines for the CY 2022 reporting period/FY 2024 payment determination and subsequent years. We are also finalizing our proposal to publicly report the measure, which will begin with the October 2022 Care Compare refresh, or as soon as technically feasible, using data collected from Q4 2021 (October 1, 2021 through December 31, 2021). However, based on public comment, we are finalizing a modification to our proposal. We will not finalize our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. Instead, we will only report the most recent quarter of data. This would result in more meaningful information that is up to date and not diluted with older data.

d. Adoption of Two Medication-Related Adverse Event Electronic Clinical Quality Measures Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25575 through 25579), we proposed to add two new medication-related adverse event electronic clinical quality measures (eCQMs) to the Hospital IQR Program measure set, beginning with the CY 2023 reporting period/FY 2025 payment determination: (1) Hospital Harm—Severe Hypoglycemia eCQM (NQF #3503e);[1017] and (2) Hospital Harm—Severe Hyperglycemia eCQM (NQF #3533e).[1018] We believe these medication-related adverse event measures are valuable patient safety measures and focus on high-priority measurement areas and patient outcomes. The measures were developed in a manner that allows them to be reported independently, but they can be considered balancing measures if a hospital chooses to report on both measures. This section includes additional details on each of the eCQMs.

(1) Hospital Harm—Severe Hypoglycemia eCQM (NQF #3503e) Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

(a) Background

Hypoglycemia is defined as a blood glucose level of less than or equal to 70 mg/dL.[1019] Hypoglycemic events are among the most common adverse drug events in hospitals.[1020] [1021] [1022] [1023] Hypoglycemia can cause a wide range of symptoms, including mild symptoms of dizziness, sweating, and confusion to more severe symptoms such as seizure, tachycardia, or loss of consciousness.[1024] [1025] Most individuals with hypoglycemia recover fully, but in rare instances, hypoglycemia can progress to coma and death.[1026]

In a study examining clinical outcomes associated with hypoglycemia in hospitalized people with diabetes, patients who had at least one hypoglycemic episode (a blood glucose level of less than 50 mg/dL) were hospitalized 2.8 days longer than patients who did not experience hypoglycemia.[1027] Another retrospective cohort study showed hospitalized patients with diabetes who experienced hypoglycemia (a blood glucose level of less than 70 mg/dL) had higher medical costs (by 38.9 percent), longer length of stay (by 3.0 days), and higher odds of being discharged to a skilled nursing facility (odds ratio 1.58; 95 percent Confidence Interval 1.48–1.69) than patients with diabetes without hypoglycemia ($p < 0.01$ for all).[1028] Hypoglycemia is associated with higher in-hospital mortality, increased length of stay, and consequently, increased resource utilization.[1029]

The rate of severe hypoglycemia (a blood glucose level of less than 40 mg/dL) varies across hospitals, indicating an opportunity for improvement in care.[1030] [1031] [1032] [1033] Severe hypoglycemia rates have been reported to range from 2.3–5 percent of

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[1016] Centers for Disease Control and Prevention. How COVID–19 Spreads. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1017] CMS eCQM Measure ID: CMS816v1.

[1018] CMS eCQM Measure ID: CMS871v1.

[1019] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1020] Lipska KJ, Ross JS, Wang Y, et al. National trends in US hospital admissions for hyperglycemia and hypoglycemia among medicare beneficiaries, 1999 to 2011. JAMA Intern Med. 2014; 174(7):1116–1124. doi:10.1001/jamainternmed.2014.1824.

[1021] McCoy RG, Lipska KJ, Herrin J, Jeffery MM, Krumholz HM, Shah ND. Hospital Readmissions among Commercially Insured and Medicare Advantage Beneficiaries with Diabetes and the Impact of Severe Hypoglycemic and Hyperglycemic Events. J Gen Intern Med. 2017; 32(10):1097–1105. doi:10.1007/s11606–017–4095–x.

[1022] Office of the Inspector General (OIG). (2010). Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. Available at: *https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf.*

[1023] Wexler, D.J., Meigs, J.B., Cagliero, E., Nathan, D.M., & Grant, R.W. (2007). Prevalence of hyper and hypoglycemia among inpatients with diabetes: A national survey of 44 U.S. hospitals. Diabetes Care, 30(2): 367–369.

[1024] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(1):16–38.

[1025] Turchin, A., Matheny, M.E., Shubina, M., Scanlon, J.V., Greenwood, B., & Pendergrass, M.L. (2009). Hypoglycemia and clinical outcomes in patients with diabetes hospitalized in the general ward. Diabetes Care, 32(7): 1153–57.

[1026] Diabetes Control and Complications Trial Research Group. (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. New England Journal of Medicine, 329(14): 977–86.

[1027] Turchin, A., Matheny, M.E., Shubina, M., Scanlon, J.V., Greenwood, B., & Pendergrass, M.L. (2009). Hypoglycemia and clinical outcomes in patients with diabetes hospitalized in the general ward. Diabetes Care, 32(7): 1153–57.

[1028] Curkendall, S.M., Natoli, J.L., Alexander, C.M., Nathanson, B.H., Haidar, T., & Dubois, R.W. (2009). Economic and clinical impact of inpatient diabetic hypoglycemia. Endocrine Practice, 15(4): 302–312.

[1029] Krinsley, J.S., Schultz, M.J., Spronk, P.E., van Braam Houckgeest, F., van der Sluijs, J.P., Melot, C. & Preiser, J.C. (2011). Mild hypoglycemia is strongly associated with increased intensive care unit length of stay. Ann Intensive Care, 1, 49.

[1030] Hospital Harm—Severe Hypoglycemia (NQF #3503e) Available at: *http://www.qualityforum.org/ProjectTemplate Download.aspx?SubmissionID=3503.*

[1031] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). Inpatient glucose control: A glycemic survey of 126 U.S. hospitals. Journal of Hospital Medicine, 4(9): E7–E14.

[1032] Egi M, Bellomo R, Stachowski E, et al. Hypoglycemia and outcome in critically ill patients. Mayo Clin Proc. 2010; 85(3):217–224. doi:10.4065/mcp.2009.0394.

[1033] Krinsley JS, Grover A. Severe hypoglycemia in critically ill patients: risk factors and outcomes. Crit Care Med. 2007 Oct; 35(10):2262–7.

hospitalized patients with diabetes, and from 0.4 percent of non-intensive care unit (ICU) patient days to 1.9 percent of ICU patient days.[1034] [1035] [1036] Severe hypoglycemic events are largely avoidable by careful use of anti-diabetic medication and close monitoring of blood glucose values.[1037] [1038] [1039]

Although there are many occurrences of hypoglycemia in hospital settings and many such events are preventable, there is currently no measure in a CMS quality program that quantifies how often hypoglycemic events happen to patients while in inpatient acute care. The AHRQ identified insulin and other hypoglycemic agents as high-alert medications and associated adverse drug events to be included as a measure in the Medicare Patient Safety Monitoring System (MPSMS), signifying the importance of measuring this hospital harm.[1040] [1041] Unlike the MPSMS, which relies on chart-abstracted data, the Hospital Harm—Severe Hypoglycemia eCQM identifies hypoglycemic events using direct extraction of structured data from the EHR. In addition, the National Action Plan for Adverse Drug Event Prevention highlighted the opportunity that exists for healthcare quality reporting measures and meaningful utilization of EHR data to advance prevention of hypoglycemic adverse drug events.[1042]

To address gaps in measurement, we developed the Hospital Harm—Severe Hypoglycemia eCQM, an outcome measure that would identify the rates of severe hypoglycemic events using direct extraction of structured data from the EHR. We believe this measure will provide reliable and timely measurement of the rate at which severe hypoglycemia events occur in the setting of hospital administration of antihyperglycemic medications during hospitalization, which will create transparency for providers and patients with respect to variation in rates of these events among hospitals. We believe that adopting this measure, which focuses on in-hospital severe hypoglycemic events in the setting of hospital-administered antihyperglycemic medications, has the potential to reduce preventable harm. Therefore, we proposed to adopt the Hospital Harm—Severe Hypoglycemia eCQM (NQF #3503e) beginning with the CY 2023 reporting period/FY 2025 payment determination.

(b) Overview of Measure

The Hospital Harm—Severe Hypoglycemia eCQM identifies the proportion of patients who experienced a severe hypoglycemic event, defined as a glucose test result of less than 40 mg/dL, within 24 hours of the administration of an antihyperglycemic agent, which indicates harm to a patient.[1043] The measure is intended to facilitate safer patient care, not only by promoting adherence to recommended clinical guidelines, but also by incentivizing hospitals to track and improve their practices of appropriate dosing and adequate monitoring of patients receiving glycemic control agents. Hospitals could use this measure to track and improve their practices of appropriate dosing and adequate monitoring of patients receiving glycemic control agents, and to avoid patient harm that can lead to increased risk of mortality and disability. This measure addresses the quality priority of ''Making Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measure Area of ''Preventable Healthcare Harm.'' [1044]

This measure is a re-specification of another hypoglycemia measure originally endorsed by the NQF, Glycemic Control—Hypoglycemia (NQF #2363).[1045] The original measure was not implemented as an eCQM because, at that time, limitations in the MAT did not allow for accurate expression of the Quality Data Model (QDM) components to express the measure logic or syntax as specified.[1046] Upgrades to the MAT have allowed the measure to be re-specified, producing accurate expression of the measure logic in CQL format to create a measure that can now be implemented.

The Hospital Harm—Severe Hypoglycemia (MUC18–109) measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2018.'' [1047] This measure was reviewed by the NQF MAP Hospital Workgroup in December 2018 and received conditional support pending NQF review and re-endorsement once the revised measure is fully tested.[1048] [1049] MAP stakeholders expressed concerns about the low glucose value (less than 40 mg/dL), the defined lab tests (for example, point-of-care vs. lab values), and the feasibility of the subsequent lab test for glucose within 5 minutes of the low glucose result. MAP stakeholders agreed that severe hypoglycemia events are largely avoidable by careful use of antihyperglycemic medications and blood glucose monitoring. The MAP recommended continuously assessing the low blood glucose threshold of <40mg/dL for defining harm events to assess unintended consequences.[1050]

[1034] Nirantharakumar, K., Marshall, T., Kennedy, A., Narendran, P., Hemming, K., & Coleman, J.J. (2012). Hypoglycemia is associated with increased length of stay and mortality in people with diabetes who are hospitalized. Diabetic Medicine, 29(12): e445–e448.

[1035] Wexler, D.J., Meigs, J.B., Cagliero, E., Nathan, D.M., & Grant, R.W. (2007). Prevalence of hyper and hypoglycemia among inpatients with diabetes: A national survey of 44 U.S. hospitals. Diabetes Care, 30(2): 367–369.

[1036] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). Inpatient glucose control: A glycemic survey of 126 U.S. hospitals. Journal of Hospital Medicine, 4(9): E7–E14.

[1037] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1038] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012; 97(1):16–38.

[1039] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015; 21(4):355–367.

[1040] Classen, DC, Jaser, L., Budnitz, D.S. (2010). Adverse Drug Events among Hospitalized Medicare Patients: Epidemiology and national estimates from a new approach to surveillance. Joint Commission Journal on Quality and Patient Safety, 36(1): 12–21.

[1041] New System Aims To Improve Patient Safety Monitoring. Content last reviewed October 2016. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *https://archive.ahrq.gov/news/blog/ahrqviews/new-system-aims-to-improve-patient-safety-monitoring.html*.

[1042] Office of Disease Prevention and Health Promotion. (2014). National Action Plan for Adverse Drug Event Prevention. Available at: *https://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf*.

[1043] Hospital Harm—Severe Hypoglycemia (NQF #3503e). Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3503*.

[1044] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page*.

[1045] Glycemic Control—Hyperglycemia NQF #2363. Available at: *http://www.qualityforum.org/QPS/2363e*.

[1046] Hospital Harm—Severe Hypoglycemia (NQF #3503e) Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3503*.

[1047] Measures Under Consideration List December 1, 2018. Available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88812*.

[1048] 2018–2019 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369*.

[1049] National Quality Forum, Measure Applications Partnership, MAP 2019 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx*.

[1050] Measure Applications Partnership, December 2018 NQF MAP Hospital Workgroup Preliminary Recommendations. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369*.

The MAP Coordinating Committee, which provides direction to the MAP workgroups, concurred with the recommendations of the MAP Hospital Workgroup. The measure was fully tested in six hospitals with two different EHR vendors (Epic and Cerner) at thresholds found to be feasible, reliable, valid, and scientifically acceptable by the NQF Patient Safety Standing Committee and was subsequently endorsed by the NQF Consensus Standards Advisory Committee (CSAC) in the Spring of 2019.[1051] [1052]

(c) Data Sources

The measure is an eCQM that uses data collected through the EHR. The measure is designed to be calculated by the hospitals' certified electronic health record technology (CEHRT) using the patient-level data submitted by hospitals to CMS.

(d) Measure Calculation

The Hospital Harm—Severe Hypoglycemia eCQM is an outcome measure that assesses the rate at which severe hypoglycemia events (blood glucose test result less than 40 mg/dL) caused by hospital administration of medications occur in the acute care hospital setting. The measure calculates the proportion of patients who are at risk and who had a low blood glucose test result (less than 40 mg/dL) and no subsequent confirmatory blood glucose within 5 minutes and in the normal range (greater than 80 mg/dL). Patients at risk include those who had an antihyperglycemic medication administered in the hospital within the 24 hours prior to the harm event. The measure counts only one severe hypoglycemia event per patient admission. We refer readers to the measure specifications for more detail: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

(e) Measure Cohort

The measure's cohort includes all patients ages 18 years and older at the start of the encounter, and for whom at least one antihyperglycemic medication was administered during the encounter.

(f) Denominator

The measure denominator includes all patients 18 years or older discharged from an inpatient hospital encounter during the measurement period who were administered at least one antihyperglycemic medication during their hospital stay. The measure includes inpatient admissions for patients admitted from either the emergency department or observation status, who subsequently became an inpatient. There are no denominator exclusions for this measure.

(g) Numerator

The numerator for this measure is the number of hospitalized patients with a blood glucose test result of less than 40 mg/dL (indicating severe hypoglycemia) with no repeat glucose test result greater than 80 mg/dL within 5 minutes of the initial low glucose test, and where an antihyperglycemic medication was administered within 24 hours prior to the low glucose result. We specified a glucose threshold of less than 40 mg/dL to identify only cases of severe hypoglycemia. We excluded a single severe hypoglycemic event with a repeat test of over 80 mg/dL within 5 minutes to avoid counting false positives (for example, from bedside point-of-care tests of capillary blood that might have returned an initial erroneous result). There are no other numerator exclusions for this measure.

(h) Risk Adjustment

We note risk adjustment is not applicable to the Hospital Harm-Severe Hypoglycemia eCQM. In the case of the Hospital Harm—Severe Hypoglycemia eCQM, there is evidence indicating that most hypoglycemic events of this severity (<40 mg/dL) are avoidable.[1053] [1054] [1055] [1056] Although specific patients may be particularly vulnerable to hypoglycemia in certain settings (for example, due to organ failure and not related to administration of diabetic agents), the most common causes are lack of caloric intake, overuse of anti-diabetic agents, or both.[1057] [1058] [1059] These causes are largely controllable in hospital environments, and risk can be reduced by following best practices. We will continue to evaluate the appropriateness of risk adjustment in measure reevaluation.

For more information on the Hospital Harm—Severe Hypoglycemia eCQM, we refer readers to the measure specifications available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*

We invited public comment on this proposal.

Comment: Many commenters supported adopting the Hospital Harm—Severe Hypoglycemia eCQM in the Hospital IQR Program. Commenters expressed their belief that the measure will improve both transparency and patient outcomes. A commenter highlighted that the measure can be easily implemented. A few commenters support the inclusion of the measure and emphasized the importance of glycemic control for reducing patient harm.

Response: We thank commenters for their support of and input on the inclusion of Hospital Harm—Severe Hypoglycemia (NQF #3503e) in the Hospital IQR Program measure set beginning with the CY 2023 reporting period/FY 2025 payment determination. We agree that this measure captures important quality information that is critical to patient safety and improving patient outcomes.

Comment: A commenter expressed support for the measure, but requested we conduct additional testing. A few commenters did not support the inclusion of Hospital Harm—Severe Hypoglycemia due the level of testing and requested that the measure undergo additional testing for feasibility and validity prior to finalization.

Response: We thank the commenters for their input and feedback on this measure. Measure testing was done in compliance with the NQF requirements for eCQM development. The Hospital Harm—Severe Hypoglycemia eCQM was tested in 6 hospitals representing two EHR systems that provided a good representation of hospitals across the country. This aligns with NQF's

[1051] NQF October 2019 CSAC Endorsement. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91440*.

[1052] NQF Patient Safety Standing Committee Memo to Consensus Standards Advisory Committee. Spring 2019 Cycle. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91278*.

[1053] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). Inpatient glucose control: A glycemic survey of 126 U.S. hospitals. Journal of Hospital Medicine, 4(9): E7–E14.

[1054] Moghissi, E.S., Korytkowski, M.T., DiNardo, M., et al. (2009). American Association of Clinical Endocrinologists and American Diabetes Association Consensus Statement on Inpatient Glycemic Control. Diabetes Care, 32(6):1119–1131.

[1055] Office of the Inspector General (OIG). (2010). Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. Available at: *https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf*.

[1056] Wexler, D.J., Meigs, J.B., Cagliero, E., Nathan, D.M., & Grant, R.W. (2007). Prevalence of hyper and hypoglycemia among inpatients with diabetes: A national survey of 44 U.S. hospitals. Diabetes Care, 30(2): 367–369.

[1057] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1058] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015;21(4):355–367.

[1059] Milligan PE, Bocox MC, Pratt E, Hoehner CM, Krettek JE, Dunagan WC. Multifaceted approach to reducing occurrence of severe hypoglycemia in a large healthcare system. Am J Health Syst Pharm 2015;72:1631–1641.

recommendation to conduct eCQM testing in more than one EHR system. Empirical results also showed that the measure exhibited high feasibility, reliability, and data element validity. The thresholds were found to be feasible, reliable, valid, and scientifically acceptable by the NQF Patient Safety Standing Committee and the measure was endorsed by the NQF Consensus Standards Advisory Committee (CSAC) in the Spring of 2019.[1060]

Comment: Several commenters supported the measure, but requested CMS delay the inclusion of the eCQM to allow additional time for hospitals to implement the measure. A commenter requested an 18 month delay, while others requested one additional year, recommending inclusion beginning with the CY 2024 reporting period/FY 2026 payment determination. A few commenters requested additional time to pilot the measure before formally adopting it into the Hospital IQR Program.

Response: We thank commenters for their support and input. We emphasize that the measure was proposed for inclusion beginning in the CY 2023 reporting period/FY 2025 payment determination, which will allow hospitals at least one year to prepare and implement the measure. We direct readers to the eCQI Resource Center (available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*) for the specifications for this eCQM, several other eCQMs being finalized, as well as those we sought comment on in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070).

Comment: Several commenters shared feedback on the adoption of Hospital Harm—Severe Hypoglycemia as a balancing measure to Hospital Harm—Severe Hyperglycemia. A few noted their support for the measure, recommending that we allow hospitals to choose which of the two measures to report. A commenter recommended CMS require reporting of both eCQMs. A few commenters noted that they could not support the adoption of these balancing measures as they believed they were not actually aligned.

Response: We thank commenters for their feedback. Hospitals will be able to report the Severe Hyperglycemia and Severe Hypoglycemia measures independently. Balancing measures are measures that can be used to demonstrate that an improvement in one area is not negatively impacting improvement in another area. For example, we can use these measures to assess whether an improvement in the number of severe hyperglycemia events ties to an increase in the number of severe hypoglycemia events. For that reason, while the two measures may not measure the same exact thing, we consider them to be balancing measures. We believe that both measures, regardless of the denominator used, will trend downward as improvements are made. Additionally, hospitals may self-select to report on one, both, or neither of these two eCQMs and select other eCQMs. While we do not require reporting of both measures at this time, we strongly encourage reporting of both. We will take commenters' recommendations to require one or both measures into future consideration.

Comment: A few commenters raised concern about the performance gap, as they felt the measure testing results showed little variation across the test sites.

Response: We thank the commenters for their feedback on this measure. The empirical results indicate over three-fold variation in measure rates across 6 test hospitals, which suggests a performance gap with room for improvement for this serious harm event.[1061] We will continue to evaluate and refine the measure through implementation as necessary.

Comment: A few commenters raised concerns that the measure does not include risk adjustment. A commenter requested that CMS continue to reevaluate the need for risk adjustment after the measure is implemented. Another commenter could not support the measure without appropriate risk adjustment.

Response: We thank the commenters for their feedback. We note that this measure was endorsed by NQF without risk-adjustment,[1062] due to a high level of preventability as specified (for example, ''severe hypoglycemia'' is specified as values <40 mg/dL). While specific patients may be more vulnerable to hypoglycemia in certain settings, the most common causes are lack of sufficient caloric intake, excessive or poor timing of anti-diabetic agents, or both.[1063] These causes are largely controllable in hospital environments and risk can be reduced by following clinical best practices.[1064] Therefore, we believe risk adjustment is not warranted in this case. We will continue to evaluate the appropriateness of risk adjustment as necessary.

Comment: A few commenters recommended that we incorporate continuous glucose monitoring (CGM) as an option for measurement and include additional glucose monitoring data.

Response: We thank the commenters for this feedback. In the measure specifications as proposed, the glucose lab value set includes code concepts that are nonspecific to the monitoring device used to collect the glucose level, which can include CGM test results.[1065] We may consider clarifying the language in the Guidance section of the measure specification.

Comment: A commenter recommended that we provide sufficient guidance on the time windows for ''day.''

Response: We thank the commenter for their feedback. As indicated in the measure specifications as proposed, the time window is 24 hours.[1066] For more detailed information and measure guidance, we refer readers to the measure specifications available on the eCQI Resource Center (available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*).

Comment: A few commenters recommended a change to the blood glucose level threshold for severe hypoglycemia. A few felt the threshold should be raised to the American Diabetes Association (ADA) definition of at least 54 mg/dL. A commenter felt the threshold should be raised to 70 mg/dL to have a greater impact. Another commenter felt that the measure is not truly an outcome measure.

Response: We thank the commenters for their input. The threshold of 40 mg/dL as specified for this measure aligns with that of a prior NQF-endorsed measure (Glycemic Control—

[1060] National Quality Forum. Patient Safety Final Technical Report—Spring 2019 Cycle. (2020, February). Available at: *https://www.qualityforum.org/Publications/2020/02/Patient_Safety_Final_Technical_Report_-_Spring_2019_Cycle.aspx.*

[1061] We refer readers to the NQF website for the measure specifications including testing information, available at: *https://nqfappservicesstorage.blob.core.windows.net/proddocs/27/Spring/2019/measures/3503/shared/3503.zip.*

[1062] National Quality Forum. Patient Safety Final Technical Report—Spring 2019 Cycle. (2020, February). Available at: *https://www.qualityforum.org/Publications/2020/02/Patient_Safety_Final_Technical_Report_-_Spring_2019_Cycle.aspx.*

[1063] American Diabetes Association. 14. Diabetes care in the hospital: Standards of Medical Care in Diabetes 2018. Diabetes Care 2018;41(Suppl. 1):S144–S151.

[1064] Ibid.

[1065] The Glucose Lab Test value set is available at: *https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1045.134.*

[1066] Hospital Harm—Severe Hypoglycemia eCQM specifications are available in the eCQI Resource Center at: *https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/1/cms816v1.*

Hypoglycemia (NQF #2363)),[1067] has received confirmation from the TEP,[1068] and helps to reduce false positives.[1069] This threshold is also in line with the empirical literature regarding severe hypoglycemia.[1070] [1071] [1072] Therefore, we believe that this threshold makes the measure an appropriate outcome measure for acute inpatient care among patients with diabetes, as values less than 40 mg/dL are typically associated with severe symptoms requiring external assistance for recovery.[1073] We will continue to monitor the threshold and revise the measure as necessary.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

(2) Hospital Harm—Severe Hyperglycemia eCQM (NQF #3533e) Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

(a) Background

Hyperglycemia is common among hospitalized patients, especially those with preexisting diabetes.[1074] [1075] Hyperglycemia can also affect individuals with no prior history of diabetes and may be induced by medications such as steroids, or parenteral (intravenous) or enteral (tube) feeding.[1076] Severe hyperglycemia, or an extremely elevated blood glucose level, is associated with a range of harms, including increased in-hospital mortality, infection rates, and hospital length of stay.[1077] [1078] [1079] [1080] [1081] [1082] [1083] [1084] [1085] The rate of severe hyperglycemia varies across hospitals, which suggests there are opportunities for improvement in inpatient glycemic management.[1086] [1087] Rates of inpatient severe hyperglycemic events can be considered an indicator for quality of hospital care, since inpatient hyperglycemia is largely avoidable with proper glycemic management.[1088] [1089] [1090] The use of evidence-based standardized protocols and insulin management protocols have been shown to improve glycemic control and safety.[1091] [1092] It should be noted that this measure does not aim to measure overall glucose control in hospitalized patients; rather, our goal is to assess the occurrence and extent of severe hyperglycemia.

(b) Overview of Measure

The intent of this measure is to track and improve practices of appropriate glycemic control and medication management of patients, and to avoid patient harm leading to increased risk of mortality and disability. This eCQM assesses the number of inpatient hospital days with a severe hyperglycemic event among the total qualifying hospital days for patients 18 years and older who have a diagnosis of diabetes mellitus and who either received at least one anti-diabetic medication during the hospital admission, or who had an elevated blood glucose level (>200 mg/dL) during their hospital admission. A severe hyperglycemic event is defined as a day in which a patient's blood glucose result was greater than 300 mg/dL, or a day in which a blood glucose value was not documented and was preceded by 2 consecutive days during which at least one glucose value was 200 mg/dL or greater.[1093] This measure addresses the quality priority of ''Making Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measure Area of ''Preventable Healthcare Harm.'' [1094]

The Hospital Harm—Severe Hyperglycemia in Hospitalized Patients (Hospital Harm—Severe Hyperglycemia) (MUC2019–26) measure was included in the publicly available ''List of

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[1067] Glycemic Control—Hypoglycemia (NQF #2363) specifications are available at: *https://www.qualityforum.org/QPS/2363e.*

[1068] Summary of Technical Expert Panel (TEP) Meetings March 2017 through January 2019 Hospital Harm eCQMs. June 2019; 17.

[1069] Krinsley JS, Grover A. Severe hypoglycemia in critically ill patients: risk factors and outcomes. Crit Care Med. 2007 Oct; 35(10):2262–7.

[1070] Cook, C. B., Kongable, G. L., Potter, D. J., Abad, V. J., Leija, D. E., & Anderson, M. (2009). Inpatient glucose control: a glycemic survey of 126 U.S. hospitals. *Journal of Hospital Medicine, 4*(9), E7–E14. *https://doi.org/10.1002/jhm.533.*

[1071] Egi, M., Bellomo, R., Stachowski, E., French, C. J., Hart, G. K., Taori, G., Hegarty, C., & Bailey, M. (2010). Hypoglycemia and Outcome in Critically Ill Patients. Mayo Clinic Proceedings, 85(3), 217–224. *https://doi.org/10.4065/mcp.2009.0394.*

[1072] Krinsley, J. S., & Grover, A. (2007). Severe hypoglycemia in critically ill patients: Risk factors and outcomes*. Critical Care Medicine, 35(10), 2262–2267. *https://doi.org/10.1097/01.ccm.0000282073.98414.4b.*

[1073] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1074] Swanson CM, Potter DJ, Kongable GL, Cook CB. Update on Inpatient Glycemic Control in Hospitals in the United States. Endocr Pract. 2011; 17(6):853–861.

[1075] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(1):16–38.

[1076] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1077] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1078] Corsino L, Dhatariya K, Umpierrez G. Management of diabetes and hyperglycemia in hospitalized patients. In Endotext [internet]. Available from *http://www.ncbi.nlm.nih.gov/books/NBK279093/.* Last Updated on October 1, 2017, Last Accessed 19 December 2019.

[1079] Pasquel FJ, Spiegelman R, McCauley M, et al. Hyperglycemia During Total Parenteral Nutrition: An Important Marker of Poor Outcome and Mortality in Hospitalized Patients. Diabetes Care. 2010;33(4):739–741.

[1080] Falciglia M, Freyberg RW, Almenoff PL, D'Alessio DA, Render ML. Hyperglycemia-Related Mortality in Critically Ill Patients Varies with Admission Diagnosis. Crit Care Med. 2009; 37(12):3001–3009.

[1081] Lee LJ, Emons MF, Martin SA, et al. Association of Blood Glucose Levels with In-Hospital Mortality and 30-Day Readmission in Patients Undergoing Invasive Cardiovascular Surgery. Curr Med Res Opin. 2012; 28(10):1657–1665.

[1082] King JT, Jr., Goulet JL, Perkal MF, Rosenthal RA. Glycemic Control and Infections in Patients with Diabetes Undergoing Noncardiac Surgery. Ann Surg. 2011; 253(1):158–165.

[1083] Jackson RS, Amdur RL, White JC, Macsata RA. Hyperglycemia is Associated with Increased Risk of Morbidity and Mortality after Colectomy for Cancer. J Am Coll Surg. 2012; 214(1):68–80.

[1084] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012; 97(1):16–38.

[1085] Krinsley, J.S., Schultz, M.J., Spronk, P.E., van Braam Houckgeest, F., van der Sluijs, J.P., Melot, C. & Preiser, J.C. (2011). Mild hypoglycemia is strongly associated with increased intensive care unit length of stay. Ann Intensive Care, 1, 49.

[1086] Swanson CM, Potter DJ, Kongable GL, Cook CB. Update on Inpatient Glycemic Control in Hospitals in the United States. Endocr Pract. 2011; 17(6):853–861.

[1087] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). Inpatient glucose control: A glycemic survey of 126 U.S. hospitals. Journal of Hospital Medicine, 4(9): E7–E14.

[1088] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015; 21(4):355–367.

[1089] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012; 97(1):16–38.

[1090] Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. Use of a Standardized Protocol to Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin. Qual Saf Health Care. 2006; 15(2):89–91.

[1091] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015; 21(4):355–367.

[1092] Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. Use of a Standardized Protocol to Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin. Qual Saf Health Care. 2006; 15(2):89–91.

[1093] Hospital Harm—Severe Hyperglycemia (NQF #3533e). Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3533.*

[1094] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

Measures Under Consideration for December 1, 2019.'' [1095] The MAP Hospital Workgroup reviewed the measure in December 2019 and the MAP Coordinating Committee reviewed the measure in January 2020. The measure received conditional support for rulemaking pending NQF endorsement.[1096] The MAP recommended monitoring the implementation of the measure using the severe high blood glucose threshold of >300 mg/dL for defining harm events to assess for unintended measurement consequences, such as hypoglycemia.[1097] The Hospital Harm—Severe Hyperglycemia measure has been found to be both reliable and valid by the NQF Scientific Methods Panel as well as the NQF Patient Safety Standing Committee in the Fall 2019 measure evaluation cycle.[1098] [1099] [1100] As with all quality measures we develop, testing was performed to confirm the measure feasibility, reliability, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Testing was completed using measure output from the MAT in multiple hospitals, using multiple EHR systems, with the measure shown to be both reliable and valid. In July 2020, the NQF endorsed the Hospital Harm—Severe Hyperglycemia measure.[1101]

This measure is a re-specification of another hyperglycemia measure originally endorsed by the NQF, Glycemic Control—Hyperglycemia (NQF #2362). Similar to the proposed Glycemic Control—Hypoglycemia (NQF #2363) measure, the original hyperglycemic measure was not implemented as an eCQM because, at that time, limitations in the MAT did not allow for accurate expression of the QDM components to express the measure logic or syntax as specified.[1102] [1103] Upgrades to the MAT have allowed the measure to be re-specified, producing accurate expression of the measure logic in CQL format to create a new measure that can now be implemented. We believe that this measure, which focuses specifically on severe hyperglycemic events in the hospital setting, has the potential to reduce preventable harm. Therefore, we proposed to adopt the Hospital Harm—Severe Hyperglycemia eCQM (NQF #3533e) beginning with the CY 2023 reporting period/FY 2025 payment determination.

(c) Data Sources

The measure is an eCQM that uses data collected through the EHR. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data submitted by hospitals to CMS.

(d) Measure Calculation

The Hospital Harm—Severe Hyperglycemia eCQM is an outcome measure that assesses the number of hospital days with a severe hyperglycemic event among the total qualifying hospital days for at risk inpatient encounters. A severe hyperglycemic event is defined in the measure as a blood glucose result >300 mg/dL, or a day in which a blood glucose value was not documented, and it was preceded by 2 consecutive days where at least one glucose value was >=200 mg/dL.

(e) Denominator

The denominator of at-risk encounters includes discharges from an inpatient hospital admission for all patients 18 years and older at the start of the measurement period, as well as—

- A diagnosis of diabetes that starts before or during the encounter;
- Administration of at least one dose of insulin or any anti-diabetic medication during the encounter; or
- Presence of at least one blood glucose value >200 mg/dL at any time during the encounter.

The eCQM includes inpatient encounters which began in the emergency department or in observation status.

The denominator is the total number of eligible days across all encounters that match the initial population criteria. This measure does not count the first 24-hour period after admission to the hospital (including the emergency department) or the last time period before the discharge, if it was less than 24 hours. By excluding the first 24 hours of admission, the measure allows for correction of severe hyperglycemia that was present on admission. By excluding the last time period before discharge if it was less than 24 hours, the measure accounts for the fact that hospitals may not always be able to check glucose during the last time period, especially if it is only a few hours long. Eligible encounters that exceed 10 days are truncated to equal 10 days.

(f) Numerator

The numerator is the total number of hyperglycemic days across all encounters. Hospital days are measured in 24-hour periods, starting from the time of arrival at the hospital (including the emergency department). Days with a hyperglycemic event are defined as either—

- A day with at least one blood glucose value >300 mg/dL; or
- A day in which a blood glucose value was not documented, and it was preceded by 2 consecutive days where at least one glucose value is >=200 mg/dL.

The measure does not count >300 mg/dL events the first 24-hour period after hospital arrival for admitted patients (including the emergency department) or the last time period before discharge, if it was less than 24 hours.

(g) Risk Adjustment

We note risk adjustment is not applicable to the Hospital Harm—Severe Hyperglycemia eCQM. In the case of the Hospital Harm—Severe Hyperglycemia eCQM, there is evidence indicating that most hyperglycemic events of this severity (>300 mg/dL) are avoidable.[1104] [1105] [1106] The rate of

[1095] Measures Under Consideration List December 1, 2019. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91406.*

[1096] 2019–2020 MAP Final Recommendations. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

[1097] 2019–2020 MAP Final Recommendations. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

[1098] NQF Scientific Methods Panel October 2019 Meeting Summary Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91486.*

[1099] 2019–2020 MAP Final Recommendations. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

[1100] NQF Patient Safety Standing Committee. Meeting Summary—Measure Evaluation #1 and #2—Fall 2019 Cycle (Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=92225*) 2019–2020 MAP Final Recommendations. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

[1101] Patient Safety Final Report—Fall 2019 Cycle. Available at: *https://www.qualityforum.org/Publications/2020/09/Patient_Safety_Final_Report_-_Fall_2019_Cycle.aspx.*

[1102] Glycemic Control—Hyperglycemia (NQF #2362e). Available at: *http://www.qualityforum.org/QPS/2362e.*

[1103] Hospital Harm—Severe Hyperglycemia (NQF #3533e). Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3533.*

[1104] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015; 21(4):355–367.

[1105] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(1):16–38.

[1106] Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. Use of a Standardized Protocol to

Continued

inpatient severe hyperglycemia events can be considered a marker for quality of hospital care, since inpatient severe hyperglycemia is largely avoidable with proper glycemic management.[1107] [1108] [1109] We will continue to evaluate the appropriateness of risk adjustment in measure reevaluation.

For more information on the Hospital Harm—Severe Hyperglycemia eCQM, we refer readers to the measure specifications available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*

We invited public comment on this proposal.

Comment: Many commenters expressed support for the inclusion of the Hospital Harm—Severe Hyperglycemia eCQM into the Hospital IQR Program measure set. Commenters noted their belief that the measure will increase transparency, drive improvements in care, and improve patient outcomes. A commenter appreciated that this measure can be applied broadly to various sized hospitals, and another commenter highlighted that this measure will expand the number of eCQMs available to rural and specialty hospitals for quality reporting. A commenter noted this measure is in alignment with the goals put forth in the National Action Plan for Adverse Drug Event Prevention (Action Plan). Commenters supported adoption of the measure and appreciated our commitment to align eCQMs in the Hospital IQR Program with the Promoting Interoperability Program.

Response: We thank commenters for their support and input. We agree that this measure, which captures important quality information that is critical to patient safety and improving patient outcomes, should be included in the Hospital IQR Program measure set.

Comment: Many commenters provided feedback on the implementation timeline for the measure. A few commenters agreed that the CY 2023 reporting period/FY 2025 payment determination is a reasonable and appropriate timeline for a new measure, while several commenters believed that the measure should be delayed. A commenter requested an 18 month delay, while others requested one additional year, recommending inclusion beginning with the CY 2024 reporting period and the FY 2026 payment determination.

Response: We thank the commenters for their support and input. The measure was proposed for inclusion beginning in the CY 2023 reporting period/CY 2025 payment determination, which will allow hospitals at least one year to prepare and implement the measure. We direct readers to the eCQI Resource Center (available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*) for measure specifications for this eCQM, several other eCQMs being finalized, as well as those we sought comment on in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070).

Comment: A few commenters asked for clarification on the proposed timeline for public reporting.

Response: In the FY 2021 IPPS/LTCH PPS final rule, we finalized public reporting of eCQM data beginning with eCQM data reported by hospital for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years (85 FR 58959). Consistent with our adopted policy, we plan to initially publish CY 2021 reporting period/FY 2023 payment determination eCQM data, of which there will be two quarters of data (for that payment determination year) on *https://data.medicare.gov,* or its successor website, before publishing it on the Hospital Compare website, or its successor website, sometime in the future. We did not propose any changes to this finalized policy in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 20570).

Comment: Several commenters addressed the concept of adopting the Hospital Harm—Severe Hypoglycemia as a balancing measure to Hospital Harm—Severe Hyperglycemia. A few noted their support for the measure, recommending that we allow hospitals to choose which of the two measures to report. A commenter recommended CMS require reporting of both eCQMs. A commenter recommended that we require hospitals to report on this measure, while a few others preferred that reporting on it be kept optional. A few commenters noted that they could not support the adoption of these balancing measures as they believed they were not aligned.

Response: We thank commenters for their feedback. Hospitals will be able to report the Severe Hyperglycemia and Severe Hypoglycemia measures independently. Balancing measures are measures that can be used to demonstrate that an improvement in one area is not negatively impacting improvement in another area. For example, we can use these measures to assess whether an improvement in the number of severe hyperglycemia events ties to an increase in the number of severe hypoglycemia events. For that reason, while the two measures may not measure the same exact thing, we consider them to be balancing measures. We believe that both measures, regardless of the denominator used, will trend downward as improvements are made. Additionally, we note that hospitals may self-select to report on one, both, or neither of these two finalized eCQMs and select other eCQMs. While we do not require reporting of both measures at this time, we strongly encourage reporting of both. We will take commenters' recommendations to require one or both measures into future consideration.

Comment: A few commenters had concerns about the complexity of the measure and potential difficulties in measuring severe hyperglycemia in patients. A commenter indicated that the introduction of a ''day'' into the numerator and denominator will require effort in measure calculation. This commenter additionally requested that we provide sufficient guidance on the time windows for ''day.'' A few commenters also expressed concern about the level of testing, requesting that the measure undergo additional testing for feasibility and validity prior to finalization.

Response: We appreciate commenters' feedback and recognize their concerns about the complexity of this measure. This measure is modeled on a previously NQF-endorsed measure (Glycemic Control—Hyperglycemia (NQF #2362)).[1110] The numerator has been simplified due, in part, to the concern of complexity with that previous endorsed measure.[1111] During measure testing, all data elements required for the measure calculation were tested for missing data. The missing rate of all required data elements was zero percent, suggesting that the measure calculation can be both feasible and automated, which

Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin. Qual Saf Health Care. 2006;15(2):89–91.

[1107] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015;21(4):355–367.

[1108] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(1):16–38.

[1109] Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. Use of a Standardized Protocol to Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin. Qual Saf Health Care. 2006;15(2):89–91.

[1110] Glycemic Control—Hyperglycemia (NQF #2362e). Available at: *http://www.qualityforum.org/QPS/2362e.*

[1111] Glycemic Control—Severe Hyperglycemia measure specifications are available at: *https://www.qualityforum.org/QPS/2362e.*

addresses concerns about the complexity of implementing the measure. As indicated in the measure specifications as proposed, the time window is 24 hours.[1112] For more detailed information and measure guidance, we refer readers to the measure specifications available on the eCQI Resource Center (available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*).

Furthermore, measure testing was done in compliance with the NQF requirements for eCQM development. The Hospital Harm—Severe Hyperglycemia eCQM was tested in six hospitals and three EHR systems that had good representation of hospitals across the country. This aligns with NQF's recommendation to conduct eCQM testing in more than one EHR system. As with all quality measures we develop, testing was performed to confirm the measure feasibility, reliability, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Empirical results showed that the measure exhibited high reliability and data element validity. Additionally, the measure performance rates across the six hospitals that participated in testing ranged from 8.2 percent to 19.5 percent.[1113] This variability suggested that the harm rate in some sites more than doubled the harm rate in other sites, which we believe indicates room for improvement.

Comment: A few commenters raised concerns that the measure does not include risk adjustment. A commenter requested that CMS continue to reevaluate the need for risk adjustment after the measure is implemented. Another commenter could not support the measure without appropriate risk adjustment.

Response: We thank commenters for their feedback. We note that this measure was endorsed by NQF without risk-adjustment.[1114] Evidence exists to show that most hyperglycemic events of this severity (>300 mg/dL) are avoidable.[1115] [1116] [1117] [1118] While certain patient health factors can impact glucose levels, clinical practice guidelines from the ADA, the Endocrine Society, and others have advocated for more intense monitoring and tailored treatment plans for higher risk individuals.[1119] [1120] As various causes for hyperglycemic events of this severity are controllable in hospital environments and risk can be reduced by adhering to clinical best practices, we do not think risk adjustment is warranted.[1121] Members of the measure's TEP and clinical experts including endocrinologists all agreed with this decision. We will, however, continue to evaluate the appropriateness of risk adjustment for this measure.

Comment: A few commenters recommended that CMS consider changing the proposed glucose level benchmark of ≥300 mg/dL for severe hyperglycemia to >250 mg/dL based on ADA recommendations.

Response: We appreciate the commenters' feedback and we understand the importance of aligning with clinical community standards. The measure developer's clinical experts supported using a higher threshold to define severe hyperglycemia (>300 mg/dL) as a clearer indication of patient harm. The higher threshold will likely improve the acceptability among clinicians and avoid the unintended consequence of hypoglycemia.

Comment: Several commenters supported the inclusion of the measure into the Hospital IQR Program, with the recommendation to incorporate continuous glucose monitoring (CGM) as an option for measurement and to include additional glucose monitoring data.

Response: We thank the commenters for this feedback. In the measure specifications as proposed, the glucose lab value set includes code concepts that are nonspecific to the monitoring device used to collect the glucose level, which can include CGM test results.[1122] We may consider clarifying the language in the Guidance section of the measure specification.

Comment: A commenter requested that CMS monitor the long-term implications of the COVID–19 pandemic before including the measure into the Hospital IQR Program, expressing that COVID–19 and a medication used to treat COVID–19 (dexamethasone) can cause significant hyperglycemia even in patients without a preexisting diagnosis of diabetes.

Response: We thank the commenter for their feedback. We note that under our current eCQM reporting requirements, hospitals are not specifically required to report on this eCQM—hospitals may self-select certain eCQMs. We refer readers to the FY 2021 IPPS/LTCH PPS final rule for more information on the current eCQM reporting requirements (85 FR 58939). We are finalizing our proposal as proposed to adopt this measure, but we will monitor the impact of COVID–19 and its treatment on measure performance during implementation.

Comment: A few commenters expressed that there should be sufficient guidance for eCQM reporting (specifically, QRDA I data) and implementation for a ratio eCQM.

Response: We thank the commenters for their feedback. We refer readers to the measure specifications available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*. We reiterate that the data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.cms.gov* (or other successor CMS designated websites). The CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update) also contains the technical specifications used for eCQMs

[1112] Hospital Harm—Severe Hyperglycemia measure specifications are available in the eCQI Resource Center at: *https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/1/cms871v1*.

[1113] Hospital Harm—Severe Hyperglycemia Measure Testing information is available at: *https://www.qualityforum.org/QPS/3533e*.

[1114] National Quality Forum. Patient Safety, Fall 2019 Cycle, Track 1 Measures: CDP Report. (2020, September).

[1115] Momesso DP, Costa Filho RC, Costa JLF, Saddy F, Mesquita A, Calomeni M, Silva CDS, Farret J, Vasques ML, Santos AG, Cabral APV, Ribeiro D, Reis L, Muino MFM, Vitorino RS, Monteiro CA, Tinoco E, Volschan A. Impact of an inpatient multidisciplinary glucose control management program. Arch Endocrinol Metab. 2018 Oct;62(5):514–522. doi: 10.20945/2359–3997000000071. PMID: 30462804.

[1116] Umpierrez GE, Smiley D, Hermayer K, Khan A, Olson DE, Newton C, et al. Randomized study comparing a basal bolus with a basal plus correction insulin regimen for the hospital management of medical and surgical patients with type 2 diabetes: Basal plus trial. Diabetes Care 2013;36: 2169–74.

[1117] Said E, Farid S, Sabry N, Fawzi M. Comparison on efficacy and safety of three inpatient insulin regimens for management of non-critical patients with type 2 diabetes. Pharmacology & Pharmacy 2013;4:556–65. DOI: 10.4236/pp.2013.47080.

[1118] Schroeder JE, Liebergall M, Raz I, Egleston R, Ben Sussan G, Peyser A, et al. Benefits of a simple glycaemic protocol in an orthopaedic surgery ward: A randomized prospective study. Diabetes/Metabolism Research and Reviews 2012;28 (1):71–5. DOI: 10.1002/dmrr.1217.

[1119] American Diabetes Association. *Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2020*. Diabetes Care. 2020 Jan;43(Suppl 1):S193–S202.

[1120] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(1):16–38. *Umpierrez2012EndocrineGlines*.

[1121] Ilcewicz HN, Hennessey EK, Smith CB. Evaluation of the impact of an inpatient hyperglycemia protocol on glycemic control. J Pharm Pharm Sci. 2019;22:85–92. *Ilcewicz2019GlycemicControl*.

[1122] The Glucose Lab Test value set is available at: *https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1045.134*.

and is generally made available the year prior to the reporting period.

Comment: A few commenters recommended adding new exclusion criteria, such as ICU with transient fluctuations in range and patients with diabetic ketoacidosis.

Response: We thank the commenter for their feedback and will consider this recommendation during future measure reevaluation.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

6. Removal of Five Hospital IQR Program Measures

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a discussion of our current measure removal factors. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25579 through 25582), we proposed to remove five measures from the Hospital IQR Program across the FY 2023 and FY 2026 payment determinations.

a. Removal of One Measure Under—Removal Factor 3, Availability of a More Broadly Applicable Measure (Across Settings, Populations, or the Availability of a Measure That Is More Proximal in Time to Desired Patient Outcomes for the Particular Topic): Death Among Surgical Inpatients With Serious Treatable Complications (CMS PSI–04)

The Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) measures in-hospital deaths per 1,000 elective surgical discharges, among 18 through 89 years or obstetric patients with serious treatable complications (shock/cardiac arrest, sepsis, pneumonia, deep vein thrombosis/pulmonary embolism or gastrointestinal hemorrhage/acute ulcer). We refer readers to the FY 2009 IPPS/LTCH PPS final rule where we adopted the Death Among Surgical Patients with Serious Treatable Complications (CMS PSI–04) measure for the FY 2010 payment determination and subsequent years (73 FR 48607) for more detail on this measure. In the FY 2011 IPPS/LTCH PPS final rule, under the RHQDAPU Program (the former title of the Hospital IQR Program), we harmonized two FY 2010 RHQDAPU Program quality measures, combining PSI–04 and ''Nursing Sensitive—Failure to rescue'' into a single measure renamed Death Among Surgical Inpatients with Serious Treatable Complications (75 FR 50182). The CMS PSI–04 measure is a claims-based measure which uses claims and administrative data to calculate the measure without any additional data collection from hospitals.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25579 through 25580), we proposed to remove this measure beginning with the CY 2021 reporting period/FY 2023 payment determination, because of the availability of a more broadly applicable measure—Factor 3. Specifically, in section IX.C.5.b. of the preamble of the proposed rule, we proposed the Hybrid HWM measure (NQF #3502). We refer readers to section IX.C.5.b. of the FY 2022 IPPS/LTCH PPS proposed rule and this rule for further discussion on the Hybrid HWM measure, including data sources, core clinical data elements, and measure calculation.

The Hybrid HWM measure captures more conditions or procedures than CMS PSI–04. The Hybrid HWM measure also captures mortality within 30 days of hospital admission for most conditions or procedures, compared to deaths for surgical discharges (or pregnancy, childbirth, and puerperium) as measured by CMS PSI–04. While the CMS PSI–04 measure is claims-based, the Hybrid HWM measure uses a hybrid of claims and clinical data elements from the EHR. As a result, we believe the Hybrid HWM measure is a more broadly applicable measure because it incorporates a larger set of conditions and procedures and moves toward greater use of EHR data for quality measurement. We note that removal of the CMS PSI–04 measure is contingent on the adoption of the Hybrid HWM measure.

We invited public comment on this proposal.

Comment: Several commenters supported our proposal to remove the CMS PSI–04 measure from the Hospital IQR Program measure set. A few commenters supported the shift from using a purely claims-based measure and believe that more consistent use of EHRs in healthcare and our proposal of the Hybrid HWM measure allow for the incorporation of larger data sets for greater quality measurement.

Response: We thank commenters for their support for our proposal. We agree that there is substantial value in shifting program measures towards digital quality measurement. As noted previously in section IX.C.5.b., we are finalizing our proposal to adopt the Hybrid HWM measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

Comment: A number of commenters provided input regarding the measure specifications of CMS PSI–04. Some commenters noted concerns about measure specifications, but they did not support removal of CMS PSI–04 and instead suggested refinements to the measure. A commenter recommended that instead of removing CMS PSI–04, it could be improved through updates to the current measure specifications. They suggested that improvements can be made to the measure specifications through refinements in the types of surgical patients and complications included in the measure. Furthermore, they believe that the suggested improvements could strengthen robustness of the measure. A few commenters supported removal of the measure, noting perceived flaws in the measure specifications including issues with the measure methodology.

Response: We appreciate commenters' feedback and concerns regarding the measure specifications and we thank commenters for their recommendations. We continue to support the importance of safety measures within our programs and acknowledge that the PSI–04 measure provides particular focus and granular data on the care of surgical patients, and is a measure that is not used in any other CMS quality program. Upon further consideration of the stakeholder feedback to retain the measure and consider suggested updates to the measure specifications, and in light of our continued commitment to safety, we have decided to not finalize our proposal to remove the measure and instead retain the measure in the Hospital IQR Program measure set at this time while we assess potential measure refinements. We intend to work with our measure development contractor to review the specifications of the CMS PSI–04 measure and we will continue to seek stakeholder feedback on the measure in future communication modes. We also note that any future changes to the measure would follow our previously finalized policies regarding substantive vs. non-substantive changes and we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538) for more details.

Comment: A few commenters raised concerns in respect to the clinical specifications of the measure, specifically, the population covered in the measure calculation. These commenters noted that the CMS PSI–04 measure specifically focuses on surgical outcomes, whereas the Hybrid HWM measure examines a more general population, not limited to surgery patients.

Response: We thank commenters for their input. The Hybrid HWM measure has a broad denominator definition that encompasses most surgical inpatients with therapeutic operating room procedures, meaning that most of the patients captured by the CMS PSI–04 measure would also be captured by the Hybrid HWM measure. However, the Hybrid HWM measure will report an overall hospital-wide mortality rate, and not a specific rate for surgical patients, so we understand and appreciate commenters' feedback on the value of retaining the CMS PSI–04 measure. We recognize that the more granular level of data provided by the CMS PSI–04 measure can continue to help inform hospital quality improvement initiatives. In addition, we understand that the measure data from CMS PSI–04 equips beneficiaries with more detailed information that is specific to surgical care. Therefore, as noted previously, upon consideration of commenters' feedback, we are not finalizing our proposal to remove the measure and instead are retaining CMS PSI–04 in the Hospital IQR Program measure set at this time.

Comment: A commenter did not support our proposal to remove the CMS PSI–04 measure because they believe there is value in it as an important patient safety measure. Specifically, this commenter noted that there are relatively few patient safety measures reported in the Hospital IQR Program or used in other CMS payment programs. Furthermore, this commenter noted that patient safety is a significant death risk and was therefore a high priority measure for both providers and patients. The commenter recommended that we add more patient safety measures to the Hospital IQR Program measure set.

Response: We appreciate the commenter's feedback. As stated previously, after consideration of stakeholder concerns, we are not finalizing the removal of this measure. We continue to consider patient safety and reducing hospital-acquired conditions and adverse events as high priorities as reflected in the Meaningful Measures Framework quality priority of making care safer by reducing harms caused in the delivery of care and in the Meaningful Measure 2.0 Framework priority focus on safety. Given our commitment to these priority areas, we also proposed and are finalizing for adoption in this FY 2022 IPPS/LTCH PPS final rule the Hospital Harm-Severe Hypoglycemia eCQM and the Hospital Harm-Severe Hyperglycemia eCQM. We believe these two outcome measures will help assess harm reduction efforts, contribute to improvements in reducing harm, and enhance hospital performance on patient safety outcomes. Additionally, in reference to patient safety measures in other programs, we interpret the commenter's reference to ''payment programs'' to denote CMS quality programs. We note that, for example, the Hospital-Acquired Condition Reduction Program continues to focus on patient safety for purposes of measuring the quality of care in inpatient care settings. While we are not removing the CMS PSI–04 measure at this time, we do intend to introduce additional patient safety eCQMs into the Hospital IQR Program in the future as measures that support our evolving program goals become available, and we have been focusing on measure concepts including pressure injury, falls with injury, acute kidney injury, and medication related bleeding. We will continue working with stakeholders to develop measures that focus on quality and safety.

After consideration of the public comments we received, we are not finalizing our proposal to remove the Death Rate Among Surgical Inpatients with Serious Treatable Complications (PSI–04) measure beginning with the CY 2021 reporting period/FY 2023 payment determination.

b. Removal of One Measure Under—Removal Factor 5, Availability of a Measure That Is More Strongly Associated With Desired Patient Outcomes for the Particular Topic: Exclusive Breast Milk Feeding (PC–05) (NQF #0480)

The Exclusive Breast Milk Feeding (PC–05) eCQM assesses the number of newborns exclusively fed breast milk during the newborn's entire hospitalization. For more details on the PC–05 measure, we refer readers to the FY 2015 IPPS/LTCH PPS final rule in which we adopted the measure for the Hospital IQR Program (79 FR 50242 through 50243). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 255801) we proposed to remove PC–05 beginning with the CY 2024 reporting period/FY 2026 payment determination under removal Factor 5—the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

Specifically, in keeping with our focus on maternal health, we proposed to adopt the Maternal Morbidity structural measure for inclusion in the Hospital IQR Program beginning with a shortened CY 2021 reporting period/FY 2023 payment determination. We refer readers to section IX.C.5.a. of the preamble of this final rule for more detail on that measure. We believe that the Maternal Morbidity structural measure is more strongly aligned with our current focus on maternal health than the PC–05 eCQM. The Maternal Morbidity structural measure focuses on determining hospital participation in a Statewide or national Perinatal QI Collaborative and implementation of patient safety practices or bundles within that QI initiative, which includes breastfeeding, while PC–05 targets only breastfeeding, a less holistic area of maternal health. Improving maternal health and the quality of maternal care is a priority for CMS, and we believe that the Maternal Morbidity structural measure will help achieve this desired outcome more directly than PC–05.

Further, we believe that removing PC–05 would produce a more harmonized and streamlined measure set (83 FR 41539 through 41540). Removing this measure from the Hospital IQR Program under removal Factor 5 supports the Meaningful Measures Framework because it helps the Hospital IQR Program reach a parsimonious set of the most meaningful measures available to track patient outcomes and impact (83 FR 41567). One of the Hospital IQR Program's primary benefits to patients and the public is its ability to collect and publicly report data for patients to use in making decisions about their care. At the same time, maintaining an unnecessarily large or complicated measure set including measures that may not be as meaningful to patients hampers the Hospital IQR Program's effectiveness at presenting valuable data in a useful manner (83 FR 41544). Replacing this measure with one that is more strongly associated with broader maternal health goals aligns with the Meaningful Measures Framework and allows us to continue to effectively promote quality care.

We note that, in alignment with our focus on encouraging quality of care in maternal health, we proposed to include the Maternal Morbidity structural measure as early as is practicable. Due to operational procedures required to remove PC–05, however, there will be overlap with the proposed Maternal Morbidity structural measure in the program until PC–05 would be removed. The Maternal Morbidity structural measure will have a reporting period beginning on October 1, 2021 through December 31, 2021, affecting the FY 2023 payment determination, which will overlap with PC–05 until its proposed removal for the CY 2024 reporting period/FY 2026 payment determination. We note that removal of PC–05 measure is contingent on the

adoption of the Maternal Morbidity structural measure.

We invited public comment on this proposal.

Comment: Many commenters supported our proposal to remove PC–05. Some commenters supported our proposal to remove PC–05 because removing the measure reduces administrative burden. Several commenters supported our proposal to remove PC–05 because the Hospital IQR Program is adopting the Maternal Morbidity structural measure. A few commenters supported our proposal to remove PC–05, because the costs associated with the measure outweigh the benefits of retaining it in the Hospital IQR Program. A commenter supported our proposal to remove PC–05 because of the evidence that exclusive breast feeding within the short inpatient interval is not a reliable indicator of long-term breast milk feeding success.

Response: We thank the commenters for their support. We agree and believe that removing PC–05 dovetails well with our adoption of the Maternal Morbidity measure. While we continue to believe that breast feeding is an important topic, we believe removing PC–05 will help ensure that we are moving the Hospital IQR Program forward in the least burdensome manner possible as we use new measures focused more directly on improving maternal morbidity, including the Maternal Morbidity structural measure, which is more holistic, that we are finalizing in this final rule.

Comment: A few commenters did not support our proposal to remove PC–05, because the Maternal Morbidity structural measure does not specifically focus on breastfeeding, and therefore, is not a true replacement of PC–05. A few commenters did not support our proposal to remove PC–05 because of their concern that removing it would result in less focus on and investment in supporting breastfeeding in hospitals. They also expressed concern that removing this measure would also reduce beneficiaries' ability to see which hospitals are supportive of breastfeeding.

Response: We appreciate commenters' concern and understand the commenters' position that retaining the measure may help focus attention on breastfeeding. However, we note that the Maternal Morbidity structural measure does address breastfeeding. It focuses on determining hospital participation in a State or national Perinatal QI Collaborative and implementation of patient safety practices or bundles within that QI initiative, which includes breastfeeding,[1123] whereas PC–05 targets only breastfeeding, a less holistic area of maternal health. Therefore, in an effort to expand our focus on the quality of maternal care,[1124] [1125] we are removing PC–05, which has a more narrow focus. We believe removing PC–05 will help ensure that we are moving the Hospital IQR Program forward in the least burdensome manner possible while continuing to encourage improvement in maternal care. We agree that maternal morbidity is an important topic and are working with a measure developer to develop a maternal morbidity eCQM for potential future use in the Hospital IQR Program.

Comment: A few commenters did not support our proposal to remove PC–05 because removal of this measure decreases the number of measures in the Hospital IQR Program that focus on maternal care.

Response: We appreciate the commenters' concern. We note that PC–05 is not a highly reported measure—in CY 2019 out of over 3,000 IPPS hospitals, 265 hospitals submitted eCQM data on PC–05 and 282 had a zero-denominator attestation. Nevertheless, we intend to continue to work with stakeholders to develop measures that focus on maternal health, and plan to introduce them when they become available. As discussed in section IX.C.5.a of this final rule, we are finalizing our proposal to adopt the Maternal Morbidity structural measure, which all hospitals participating in the Hospital IQR Program, will be required to report beginning with a shortened reporting period running from October 1, 2021 through December 31, 2021. This new measure specifically focuses on maternal health.

Comment: A commenter did not support our proposal to remove PC–05 because of their belief that removing PC–05 would negatively affect vulnerable populations who already have low rates of breastfeeding.

Response: We appreciate the commenter's concern related to disparities. As noted earlier, we are focused on and committed to closing the health equity gap as discussed in the Health Equity RFI in the proposed rule (86 FR 25554 through 25561) and in section IX.B. of this final rule. Specifically regarding the PC–05 measure, as mentioned, only 265 hospitals submitted eCQM data on PC–05 for the CY 2019 reporting period. While not directly focused on breastfeeding, we believe that other measures more directly focused on maternal health, including maternal morbidity outcome measures such as the eCQM focused on severe obstetrics complications previously mentioned, would be better able to target the measurement of care quality for vulnerable patient populations. We continue to believe that maternal care is a topic of vital importance, and we will continue to work with relevant stakeholders to identify measures of quality and advance improved health outcomes for maternal care.

Comment: A few commenters did not support our proposal to remove PC–05 due to concerns about: (1) Recognizing the hospitals' resource expenditure; (2) alignment with other quality reporting initiatives; and (3) providing more notice before measure adoptions. A commenter did not support our proposal to remove PC–05 because of their belief that the removal would discount the investment of resources hospitals must expend to operationalize an eCQM. A commenter observed that by removing eCQM measures, the Hospital IQR Program falls out of alignment with The Joint Commission, such that hospitals face increased burden to report on different measures for various programs. A commenter did not support our proposal to remove PC–05 and instead suggested that CMS provide a one-year prospective schedule with the list of measures they are contemplating for removal so that hospitals have time to plan accordingly.

Response: We recognize that hospitals expend resources to participate in the Hospital IQR Program. We understand the commenters' concern with removing an eCQM that has previously been reported and implemented in an existing EHR workflow. We acknowledge that changes to the Hospital IQR Program's measure set may be disruptive for hospitals that have already operationalized previously adopted measures. We appreciate hospitals' efforts to operationalize the PC–05 measure, however, we believe removing PC–05 will help ensure that we are moving the Hospital IQR Program forward in the least burdensome manner possible while continuing to encourage improvement in the quality of care provided to patients. Hospitals should feel

[1123] We refer readers to section IX.C.5.a. of the preamble of this final rule for more detailed information on the Maternal Morbidity structural measure.

[1124] HHS Press Office (2020) HHS Outlines New Plans and a Partnership to Reduce U.S. Pregnancy-related Deaths. *https://www.hhs.gov/about/news/2020/12/03/hhs-outlines-new-plans-to-reduce-us-pregnancy-related-deaths.html.*

[1125] Office of the Assistant Secretary for Planning and Evaluation (2020) HHS Initiative to Improve Maternal Health. *https://aspe.hhs.gov/initiative-to-improve-maternal-health.*

empowered to continue to use eCQMs for their own quality improvement processes and do not need CMS to calculate the measure or wait for performance feedback reports. Further, we recognize that changing our measure set may cause the Hospital IQR Program to fall out of alignment with the measure sets of other reporting systems, including The Joint Commission's (TJC's) perinatal core measure set which currently includes the PC–05 measure. We continue to consider other quality monitoring organizations' requirements as we build our own measure set, but note that the Hospital IQR Program's measure set is distinct from other reporting programs. We also note that other quality reporting initiatives may change their requirements. Furthermore, we intend to continue to use the notice and comment rulemaking process to adopt and remove measures from the Hospital IQR Program to provide stakeholders with notice of changes to our measure set.

We emphasize that the decision to remove measures from the Hospital IQR Program is an extension of our goal under the Meaningful Measures Framework to continually refine the Hospital IQR Program's measure set so as to use a parsimonious set of the most meaningful measures. We will continue working to provide hospitals with the education, tools, and resources necessary to help reduce eCQM reporting burden and more seamlessly account for the removal or addition of eCQMs.

Comment: A commenter suggested we remove PC–05 before CY 2024 to alleviate the burden of maintaining a measure that will be removed.

Response: We appreciate commenter's suggestion. Because some hospitals may have chosen to report on PC–05 over recent years, we believe it is important to allow them time to prepare to report on different eCQMs.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

c. Removal of Three Measures Under—Removal Factor 8, Costs Associated With a Measure Outweigh the Benefit of Its Continued Use in the Program

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25580 through 25581) we proposed to remove three measures under removal Factor 8, ''Costs Associated with a Measure Outweigh the Benefit of its Continued Use in the Program.'' These three measures are Admit Decision Time to ED Departure Time for Admitted Patients (ED–2); Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03); and Discharged on Statin Medication (STK–06).

(1) Admit Decision Time to ED Departure Time for Admitted Patients (ED–2)

In the FY 2016 IPPS/LTCH PPS final rule, we adopted the Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) eCQM as an option from which hospitals could choose to report to meet the self-selected eCQM data reporting requirements for the FY 2018 payment determination. We refer readers to the FY 2016 IPPS/LTCH PPS final rule for more detail on this measure (80 FR 49693 through 49698). The ED–2 eCQM evaluates the median time in minutes from admit decision time to time of departure from the emergency department (ED) for ED patients admitted to inpatient status.

A recently published systematic review by Boudi, et al. of 12 individual studies examined the association between ED boarding time (the time between the admission decision and departure from the ED) and in hospital mortality (IHM). Although the authors noted a tendency toward an association, they did not find strong evidence for an association between ED boarding and IHM.[1126] Six of the studies reviewed showed an association between ED boarding time and IHM, five showed no association, and the remaining study demonstrated an association for patients admitted to non-ICU wards and no association for patients admitted to ICU status.[1127]

The authors indicated there is variability in what is considered a cut-off time to define extended ED boarding time or prolonged ED LOS and stated that, in the U.S., prolonged ED visits have been defined as over 6 hours.[1128] In several of the studies in this systematic review demonstrating an association between ED boarding and IHM, the researchers compared mortality between patients with a boarding time period of less than 6 hours and those with a boarding time period equal or greater than 6 hours (360 minutes). We compared these timeframes to hospital performance data for the chart-abstracted version of ED–2,[1129] using the most recent data in the *Care Compare* downloadable data base for timely and effective care from January 1, 2019 through December 31, 2019. Those results show that the national average for the ED–2 median reported boarding times is 101 minutes; the ED–2 90th percentile is 31 minutes; and only 37 out of 4,028 (0.92 percent) hospitals that reported on ED–2 had an ED–2 median time equal to or greater than 360 minutes. Thus, the *Care Compare* data indicate that most hospitals do not report median boarding times that correspond with this 6-hour cutoff.

Boudi's systematic review is consistent with previous research finding conflicting results related to the association between ED crowding and inpatient mortality. For example, a study by Derose, et al. found no association between measures indicating ED crowding and inpatient mortality after controlling for patient characteristics.[1130]

In light of the inconsistency in research findings, we reassessed the value of retaining the ED–2 eCQM in the Hospital IQR Program and proposed to remove this measure, beginning with the CY 2024 reporting period/FY 2026 payment determination, under Factor 8, ''The costs associated with a measure outweigh the benefit of its continued use in the program.'' Pursuant to removal Factor 8, we strive to ensure that the Hospital IQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program (83 FR 41540). We believe that costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For healthcare providers, the costs include maintaining the general administrative knowledge needed to report this measure as well as the costs associated with implementing

[1126] Boudi Z, Lauque D, Alsabri M, Ostlundh L, Oneyji C, Khalemsky A, et al. (2020) Association between boarding in the emergency department and in-hospital mortality: A systematic review. PLoS ONE 15(4): e0231253. *https://doi.org/10.1371/journal.pone.0231253.*

[1127] Boudi Z, Lauque D, Alsabri M, Ostlundh L, Oneyji C, Khalemsky A, et al. (2020) Association between boarding in the emergency department and in-hospital mortality: A systematic review. PLoS ONE 15(4): e0231253. *https://doi.org/10.1371/journal.pone.0231253.*

[1128] The authors note there is a lack of a unique cut-off time to define EDB and state that, ''[f]urther well-controlled, international multicenter studies are needed to demonstrate . . . whether there is a specific EDB time cut-off that results in increased IHM.''

[1129] The chart-abstracted version of ED–2 was finalized for removal in the FY 2019 IPPS/LTCH PPS final rule for the FY 2022 payment determination (83 FR 41567).

[1130] Derose S, Gabayan G, Chiu V, Yiu S, Sun B. (2014) Emergency Department Crowding Predicts Admission Length-of-Stay But Not Mortality in a Large Health System. Med Care. 2014 July; 52(7): 602–611. doi:10.1097/MLR.0000000000000141. This study of the impact of ED system crowding measures on outcomes concluded that, after controlling for patient characteristics, there was no association between measures of ED crowding and inpatient mortality.

and maintaining measure specifications in hospitals' EHR systems for all the eCQMs available for use in the Hospital IQR Program (83 FR 41568). We also recognize that CMS expends resources when maintaining information collection systems and analyzing reported data. Removing these measures will reduce provider and program costs alike. Given that recent studies indicate an inconclusive association between ED boarding times and adverse outcomes such as in-hospital mortality, the cost of the current expenditure outweighs the benefit of continued used of ED–2. Additionally, due to the operational limitations of introducing and removing eCQMs associated with the lifecycle of such measures, we proposed to remove this measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

We invited public comments on this proposal.

Comment: Many commenters supported our proposal to remove the ED–2 eCQM. Some commenters appreciated that the removal would reduce burden on hospitals and others agreed that the costs associated with ED–2 outweigh the benefit of its continued use in the Hospital IQR Program. A few commenters questioned whether boarding times accurately reflect quality of care and some suggested that quality of care is more impacted by external factors such as access to behavioral health treatment, patterns of primary care deliver, and nursing shortages.

Response: We thank the commenters for the support of our proposal to remove the ED–2 eCQM. While we continue to believe that prolonged ED board times is an important issue, we agree that the Admit Decision Time to ED Departure Time for Admitted Patients measure has had inconclusive associations with adverse outcomes such as in-hospital mortality and the quality of care in the inpatient setting.[1131] We acknowledge the commenters' perspective that other factors, in addition to boarding times, impact outcomes and note that this measure was not intended to suggest otherwise. We note that we will continue measuring ED boarding times in the outpatient setting via the OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496) measure, in the Hospital Outpatient Quality Reporting (OQR) Program (75 FR 72094). We appreciate the commenters' feedback and will take it into consideration as we continually refine the measure sets for our quality programs.

Comment: Several commenters did not support the proposal to remove ED–2. Many disagreed with the conclusion drawn regarding the relation between ED boarding and in-hospital mortality (IHM) as discussed in the Boudi, et al. article. Several commenters also expressed their belief that the measure is reliable, informative, and assesses a critical area of care.

Response: We thank the commenters for their feedback. We agree that ED boarding is an important area of care, and as noted earlier, we will continue measuring ED boarding times in the outpatient setting via the OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients measure (NQF #0496) (75 FR 72094). We recognize and appreciate the commenters' concerns about ED boarding of patients being associated with events such as ambulance diversion, preventable medical errors, lower patient satisfaction, and patient morbidity and mortality. While a number of studies assess the impacts of ED boarding, it is worth noting that reported impacts of ED boarding may vary by clinical condition, clinical interventions, and inpatient admission location.[1132] [1133]

However, as discussed in the proposed rule, we believe that ED boarding times have inconclusive associations with adverse outcomes such as in-hospital mortality. While the metanalysis by Boudi, et al., did find an association between prolonged ED boarding times and mortality in some of the included studies, Boudi et al. reported that this finding was inconsistent across studies, leading the authors to note that there was only a tendency toward an association, as opposed to strong evidence for an association between ED boarding and in-hospital mortality.[1134] Those studies that did demonstrate a tendency toward an association found the association was more evident when ED boarding times exceeded 6 hours, 360 minutes.[1135] As we discussed in the proposed rule (86 FR 25580 through 25581), the most recently available data in the *Care Compare* downloadable data base for timely and effective care from January 1, 2019 through December 31, 2019 showed that the national average for the ED–2 median reported boarding times is 101 minutes for Hospital IQR Program hospitals; the ED–2 90th percentile is 31 minutes; and only 37 out of 4,028 (0.92 percent) hospitals that reported on ED–2 had a median time equal to or greater than 360 minutes. The data from *Care Compare* suggests that for most hospitals, reported median ED boarding times are not in excess of 6 hours. This coupled with most literature demonstrating an association between mortality and ED boarding times in excess of 6 hours, limits the value of the ED–2 measure for demonstrating opportunities to further decrease ED boarding times to a level that would significantly impact mortality rates.

Comment: Several commenters disagreed with our use of removal Factor 8, noting their belief that the benefit of retaining an established measure does not outweigh the costs associated with the measure. A few commenters specifically noted their belief that this measure is beneficial because of the correlation between ED boarding times and patient clinical outcomes, beyond just in-hospital mortality. Several commenters expressed that they continued to find value in the measure, do not find it burdensome to collect, and were concerned that removing the measure discounts the investment of resources hospitals have expended in operationalizing ED–2.

Response: Despite our proposal to remove ED–2, we continue to believe that patient care and flow in the ED is an important topic, in part because prolonged ED boarding times can impact outcomes other than mortality. We agree with commenters that ED boarding time is an important issue, and we remind readers that it is assessed in

[1131] Boudi Z, Lauque D, Alsabri M, Ostlundh L, Oneyji C, Khalemsky A, et al. (2020) Association between boarding in the emergency department and in-hospital mortality: A systematic review. PLoS ONE 15(4): e0231253. *https://doi.org/10.1371/journal.pone.0231253.*

[1132] Boudi Z, Lauque D, Alsabri M, Ostlundh L, Oneyji C, Khalemsky A, et al. (2020) Association between boarding in the emergency department and in-hospital mortality: A systematic review. PLoS ONE 15(4): e0231253. *https://doi.org/10.1371/journal.pone.0231253* Boudi, et al. and Derose, et al.).

[1133] Derose S, Gabayan G, Chiu V, Yiu S, Sun B. (2014) Emergency Department Crowding Predicts Admission Length-of-Stay But Not Mortality in a Large Health System. Med Care. 2014 July; 52(7): 602–611. doi:10.1097/MLR.0000000000000141. This study of the impact of ED system crowding measures on outcomes concluded that, after controlling for patient characteristics, there was no association between measures of ED crowding and inpatient mortality.

[1134] Boudi Z, Lauque D, Alsabri M, Ostlundh L, Oneyji C, Khalemsky A, et al. (2020) Association between boarding in the emergency department and in-hospital mortality: A systematic review. PLoS ONE 15(4): e0231253. *https://doi.org/10.1371/journal.pone.0231253.*

[1135] Boudi Z, Lauque D, Alsabri M, Ostlundh L, Oneyji C, Khalemsky A, et al. (2020) Association between boarding in the emergency department and in-hospital mortality: A systematic review. PLoS ONE 15(4): e0231253. *https://doi.org/10.1371/journal.pone.0231253.*

the Hospital OQR Program via the OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients measure(75 FR 72094). We also support hospitals implementing interventions to minimize ED boarding time to minimize the adverse impact of ED boarding times independent of the requirements of the Hospital IQR Program. We will continue to work with relevant stakeholders to identify measures of quality and advance improved health outcomes for ED patients. As described in an earlier response, the benefit of maintaining the ED–2 measure in the Hospital IQR Program is limited, because most hospitals median ED boarding times are not in excess of 6 hours, limiting the value of the ED–2 measure for demonstrating opportunities to further decrease ED boarding times to a level that would significantly impact mortality rates. This, coupled with most literature demonstrating an association between mortality and ED boarding times in excess of 6 hours, limits the value of the ED–2 measure for demonstrating opportunities to further decrease ED boarding times to a level that would significantly impact mortality rates. Therefore, we believe the benefit of maintaining the measure is outweighed by the costs associated with maintaining it.

In addition, we acknowledge the commenters' concern regarding removing an eCQM that has previously been reported and implemented in an existing EHR workflow, and we recognize the time, effort, and resources that hospitals expend on reporting these measures. We appreciate hospitals' efforts to operationalize the ED–2 measure. We respectfully disagree that removing the ED–2 eCQM would not reduce some burden on providers and their health IT vendors. Focusing on a more streamlined measure set gives hospitals and their health IT vendors more time and resources to accommodate new reporting requirements by reducing measure maintenance and specification requirements. Removing targeted measures from the Hospital IQR Program is consistent with our goal under the Meaningful Measures Framework to continually refine the measure set as appropriate. We believe removing ED–2 will help ensure that we are moving forward in the least burdensome manner possible while maintaining a parsimonious set of the most meaningful quality measures and while continuing to incentivize improvement in the quality of care provided to patients. We will continue working to provide hospitals with the education, tools, and resources necessary to help reduce eCQM reporting burden and more seamlessly account for the removal or addition of eCQMs.

Comment: A few commenters were concerned about the timeline for and timeliness of removing ED–2. A commenter questioned why we would remove an eCQM in light of our goal in the Meaningful Measures Framework 2.0 to fully transition to digital quality measures (dQMs) by 2025. Another commenter expressed concern that the measure data had not yet been publicly reported and recommended that we wait to remove the measure until after the public has had an opportunity to evaluate the measure data. Another suggested we remove ED–2 before CY 2024 to alleviate the burden of maintaining a measure that will be removed.

Response: Pursuant to Meaningful Measures 2.0, we are indeed emphasizing digital quality measurement and are working toward fully digital quality measurement by 2025.[1136] However, our goal to transition to digital quality measures runs parallel with our goal of moving the program forward in the least burdensome manner possible while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Consistent with these goals, we believe it is appropriate to remove certain eCQMs to develop a more streamlined measure set. As some hospitals may have chosen to report on ED–2 over recent years, we believe it is important to allow them time to prepare to report on different eCQMs. We acknowledge that the eCQM data has not yet been publicly reported. We refer readers to 85 FR 58953 through 58959 for a more detailed discussion of the Hospital IQR Program's plan and policy for publicly reporting eCQM data. Nonetheless, in keeping with our initial proposal, and our goal of maintaining a parsimonious measure set, we continue to believe it is appropriate to remove ED–2 at this time. We appreciate commenters' suggestions and will take them into consideration as we continually refine the measure sets for our quality programs.

Comment: A commenter did not support the removal of ED–2 because it was concerned that its removal would disincentivize hospitals from maintaining low ED boarding times.

Response: We appreciate the commenter's concern, but respectfully disagree that the removal will result in hospitals not working to maintain low boarding time. We are confident that hospitals are committed to providing high quality care to patients, and we do not have any indication that they will stop trying to reduce emergency department board times. However, we encourage commenters to submit any evidence suggesting that removing this measure leads to a reduction in desired clinical behavior. We will continue to monitor for stakeholder feedback about reduction in desired clinical behavior. We support hospitals continuing to use the ED–2 eCQM for their own quality improvement activities even if the measure is not part of the Hospital IQR Program's measure set, including to improve ED boarding times, especially for those that can continue to use it at a minimal cost. Additionally as mentioned earlier, we continue to encourage hospitals to focus on improving ED boarding times in the outpatient setting; we will continue measuring ED boarding times in the Hospital OQR Program setting via the OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients measure (75 FR 72094).

Comment: A few commenters did not support our proposal to remove ED–2 due to concerns it would reduce the options for reporting. A commenter specified that rural and critical access hospitals would be particularly affected.

Response: We thank the commenters for their feedback. We acknowledge that facilitating quality improvement for rural hospitals, small hospitals, and critical access hospitals[1137] and can present unique challenges and is a high priority under the Meaningful Measures Framework. We highlight that we are finalizing our proposal to adopt the Hospital Harm—Severe Hyperglycemia eCQM and the Hospital Harm—Severe Hypoglycemia into the Hospital IQR Program measure set, which commenters supported in part because it would expand the number of eCQMs available to rural and specialty hospitals. We refer readers to sections IX.C.5.d.1. and IX.C.5.d.2. for more detail on our finalized proposals to adopt the Hospital Harm—Severe Hypoglycemia eCQM and Hospital Harm—Severe Hyperglycemia eCQM.

[1136] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[1137] We note that under section 1886(b)(3)(B)(viii) of the Act, only subsection (d) hospitals are required to submit data to the Hospital IQR Program. Critical access hospitals participate in the electronic reporting of CQMs under the Promoting Interoperability Program.

We intend to introduce additional eCQMs into the program and will work with stakeholders to consider and develop measures that are appropriate for use by small and rural hospitals.

Comment: A commenter observed that by removing eCQM measures, the Hospital IQR Program falls out of alignment with The Joint Commission, such that hospitals face increased burden to report on different measures for various programs. A few commenters recommended that CMS provide a one-year prospective schedule with the list of measures they are considering for removal so that hospitals have time to plan accordingly.

Response: We recognize that by changing our measure set, the Hospital IQR Program and measure sets of other reporting systems become misaligned. We seek to align efforts as much as possible, but the Hospital IQR Program is separate and distinct from The Joint Commission. While we intend to continue to consider other quality monitoring organizations' requirements in building our own measure set, the decision to remove measures from the Hospital IQR Program is an extension of our goal under the Meaningful Measures Framework to continually refine the Program's measure set so as to use a parsimonious set of the most meaningful measures.

We acknowledge the commenters' concern with removing an eCQM that has previously been reported and implemented in an existing EHR workflow, and we recognize the time, effort, and resources that hospitals expend on reporting these measures. However, the decision to remove measures from the Hospital IQR Program is an extension of our goal under the Meaningful Measures Framework to continually refine the measure set so as to use a parsimonious set of the most meaningful measures. Additionally, we direct the commenter to the MAP (*https://www.qualityforum.org/map/*) and its review of potential measures for removal. We intend to continue to use the notice and comment rulemaking process to adopt and remove measures from the Hospital IQR Program to provide stakeholders with notice of changes to our measure set. We will continue working to provide hospitals with the education, tools, and resources necessary to help reduce eCQM reporting burden and more seamlessly account for the removal or addition of eCQMs.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

(2) Stroke-Related Electronic Clinical Quality Measures (eCQMs)

In the FY 2022 IPPS/LTCH PPS proposed rule (86 25581 through 25582) we proposed to remove two stroke-related eCQMs:

- Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03) (adopted in the set of eCQMs from which hospitals self-select for Hospital IQR Program reporting in the FY 2016 IPPS/LTCH PPS final rule, 80 FR 49693 through 49698); and
- Discharged on Statin Medication (STK–06) (adopted in the set of eCQMs from which hospitals self-select for Hospital IQR Program reporting in the FY 2016 IPPS/LTCH PPS final rule, 80 FR 49693 through 49698).

We proposed to remove STK–03 and STK–06 under removal Factor 8, ''the costs associated with a measure outweigh the benefit of its continued use in the program.'' Under removal Factor 8, we strive to ensure that the Hospital IQR Program measure set aligns with the Meaningful Measures Framework goal of promoting improved health outcomes for beneficiaries while minimizing the overall costs associated with the program (83 FR 41540). We assessed the relative costs and benefits for both measures as described in detail in this rule.

As we assessed the relative benefits of these measures, we recognized that our measure set contains a high proportion of stroke related eCQMs. As previously finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58931), we have a total of nine eCQMs, four of which are stroke related. In order to achieve a more parsimonious measure set, we believe it is appropriate to reduce the portfolio of stroke-related eCQMs. We continue to believe that ensuring appropriate pharmacotherapy for stroke patients is an important topic and we will continue to work with relevant stakeholders to identify measures of quality and advance improved health outcomes for stroke patients. Within the eCQM portfolio of stroke measures, we identified STK–03 and STK–06 as candidates for removal based on specific considerations described in this rule.

For STK–03 specifically, the patient population (patients prescribed anticoagulation therapy, which is a type of antithrombotic therapy), can be considered a subpopulation of the global population of ischemic stroke patients captured under the STK–02 eCQM, which measures the number of patients prescribed antithrombotic therapy at hospital discharge.[1138] Further, the results of our internal review of the CY 2019 eCQM reporting indicate that fewer hospitals chose to report STK–03 than any of the other remaining three stroke-related eCQMs. In contrast, STK–02 was the most reported of the four stroke-related eCQMs for the CY 2019 eCQM reporting period. Though the STK–02 eCQM does not provide the same level of granularity as the STK–03 eCQM, we believe that the low reporting rate of STK–03 coupled with the overlap in patient populations means that the benefits of maintaining both measures in the Hospital IQR Program measure set has been reduced. Given these reduced benefits, we now believe that the costs associated with this measure outweigh the benefits of retaining this measure in the Hospital IQR Program measure set.

For STK–06 specifically, which assesses percentage of patients discharged on statin medication, we found that the updated 2019 American Heart Associations (AHA)/American Stroke Association (ASA) stroke guidelines on antiplatelet treatment indicate that STK–06 is not the most suitable measure for improving patient outcomes in stroke treatment during the acute period.[1139] [1140] We believe the body of evidence supporting the benefits of retaining STK–06 has been weakened by the findings of the AHA/ASA stroke guidelines. This is because the strongest recommendations and quality of evidence are for administration of aspirin in patients with Acute Ischemic Stroke within 24 to 48 hours after onset. Furthermore, there is only moderate quality evidence to continue STK–06, the measure of ischemic stroke patients who are prescribed or continue to take statin medication at hospital discharge.[1141] [1142]

[1138] D. Becker. 2013 Antithrombotic Drugs: Pharmacology and Implications for Dental Practice. Anesth Prog. 2013 Summer; 60(2): 72–80. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3683884/*.

[1139] Kennedy J, Hill MD, Ryckborst KJ, Eliasziw M, Demchuk AM, Buchan AM; FASTER Investigators. Fast Assessment of Stroke and Transient Ischaemic Attack to Prevent Early Recurrence (FASTER): A randomised controlled pilot trial. Lancet Neurol. 2007; 6:961–969. doi:10.1016/S1474–4422(07)70250–8.

[1140] Yoshimura S, Uchida K, Daimon T, Takashima R, Kimura K, Morimoto T; on behalf of the ASSORT Trial Investigator. Randomized controlled trial of early versus delayed statin therapy in patients with acute ischemic stroke: ASSORT Trial (Administration of Statin on Acute Ischemic Stroke Patient). Stroke. 2017;48:3057–3063. doi:10.1161/STROKEAHA.117.017623.

[1141] Powers WJ, Rabinstein AA, Ackerson T, Adeoye OM, Bambakidis NC, Becker K, Biller J, Brown M, Demaerschalk BM, Hoh B, Jauch EC, Kidwell CS, Leslie-Mazwi TM, Ovbiagele B, Scott PA, Sheth KN, Southerland AM, Summers DV, Tirschwell DL; on behalf of the American Heart Association Stroke Council. Guidelines for the early management of patients with acute ischemic stroke:

Lastly, other measures like STK–02, Discharged on Antithrombotic Therapy, and STK–05, Antithrombotic Therapy by The End of Hospital Day 2, already support our efforts to improve care and patient outcomes in the acute period. Taken together we believe that the benefit of retaining STK–06 has been reduced. Given these reduced benefits, we now believe that the costs associated with this measure outweigh the benefits of retaining this measure in the Hospital IQR Program measure set.

We believe that costs are multifaceted and include the burden associated with reporting as well as costs related to program implementation and maintenance, which are applicable both to providers and CMS (83 FR 41540). Removing STK–03 and STK–06 under Factor 8 will eliminate costs associated with implementing and maintaining these measures for the Hospital IQR Program. For healthcare providers, the costs associated with STK–03 and STK–06 include maintaining the general administrative knowledge needed to report these measures as well as the costs associated with implementing and maintaining measure specifications in hospitals' EHR systems for all the eCQMs available for use in the Hospital IQR Program (83 FR 41568). We also recognize that CMS expends resources when maintaining information collection systems and analyzing reported data. Removing these measures will reduce provider and program costs alike.

In summary, removing STK–03 and STK–06 will reduce the costs associated with them in the Hospital IQR Program while still maintaining an efficient measure set that continues to effectively promote quality care. Removing STK–03 and STK–06 supports using a parsimonious set of the most meaningful measures available to track patient outcomes and impact, in keeping with the Meaningful Measures Framework (83 FR 41567). Maintaining an unnecessarily large or complicated measure set including measures that are not meaningful to consumers and caregivers hampers the Hospital IQR Program's effectiveness (83 FR 41544). Additionally, due to the operational feasibility of introducing and removing eCQMs, we proposed to remove both measures beginning with the CY 2024 reporting period/FY 2026 payment determination.

We invited public comment on these proposals. We address the comments on each measure separately below.

(a) Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03)

Comment: Many commenters generally supported our proposal to remove STK–03. Several commenters supported our proposal to remove STK–03 because removing the measure reduces administrative burden, and a few commenters specifically agreed with removing it under removal Factor 8 because they agreed that costs associated with the measure outweigh the benefits of retaining it in the Hospital IQR Program. A commenter supported our proposal to remove STK–03 because the removal will add balance to the core set of eCQMs available for reporting.

Response: We thank the commenters for their support of our proposal to remove STK–03. While we agree with commenters that removal Factor 8 would be an appropriate way to remove the STK–03 eCQM, we are not finalizing our proposal because we agree with the more compelling rationale provided by commenters to retain the STK–03 eCQM. Most notably, commenters identified two reasons to retain STK–03 in addition to STK–02. First, commenters highlighted their belief that the STK–02 measure does not specifically target prescribing of anticoagulation therapy. Commenters expressed their concern that removing STK–03 could thereby result in fewer stroke patients receiving appropriate anticoagulant therapy. Second, commenters identified that STK–03 distinguishes between the general category of antithrombotic therapy and the specific subset of anticoagulant therapy, whereas STK–02 does not ensure that stroke patients with atrial fibrillation are appropriately prescribed an anticoagulant as guidelines recommend. In addition, other commenters emphasized that ischemic stroke patients are not all the same, and that their treatment protocols might vary. For example, patients with non-cardioembolic ischemic stroke should be treated with antiplatelet medication, rather than anticoagulation. Upon further consideration of commenter feedback, we have decided not to finalize our proposal to remove STK–03 eCQM. These specific comments and our responses are discussed in more detail later in section.

Comment: A number of commenters did not support our proposal to remove STK–03. Commenters asserted their belief that the STK–02 measure does not specifically target prescribing of anticoagulation therapy to patients at discharge. Commenters identified that ischemic stroke patients are not all the same, noting their belief that patients with non-cardioembolic ischemic stroke should be treated with antiplatelet medication, rather than anticoagulation. Commenters also pointed out the distinction that the STK–03 eCQM makes between the general category of antithrombotic therapy and the specific subset of anticoagulant therapy, whereas STK–02 does not ensure that stroke patients with atrial fibrillation are appropriately prescribed an anticoagulant as guidelines recommend. Commenters expressed their belief that anticoagulation has historically been dramatically underutilized for stroke prevention in patients with atrial fibrillation, such that prescribing it at discharge is an important opportunity to improve appropriate use in these patients. Commenters were concerned that removing STK–03 could result in fewer stroke patients receiving appropriate anticoagulant therapy.

Response: We appreciate commenters' concerns. We have confidence that hospitals are committed to providing good quality care to stroke patients, and we do not have any indication that they will stop doing so in these areas for which the quality of care has become standard practice. After considering stakeholder concerns, we will retain the STK–03 eCQM in the Hospital IQR Program's measure set and are thus not finalizing the removal in this final rule.

Comment: A commenter observed that by removing the STK–03 eCQM measure, the Hospital IQR Program falls out of alignment with The Joint Commission, such that hospitals face increased burden to report on different programs for various programs.

Response: We recognize that by changing our measure set, the Hospital IQR Program and measure sets of other reporting systems become misaligned. We seek to align efforts as much as possible, but the Hospital IQR Program is separate and distinct from The Joint Commission. While we intend to continue to consider other quality monitoring organizations' requirements in building our own measure set, the decision to remove measures from the Hospital IQR Program is an extension of our goal under the Meaningful Measures Framework to continually refine the Program's measure set so as to use a parsimonious set of the most meaningful measures. However, we note that after consideration of stakeholder

2019 update to the 2018 guidelines for the early management of acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2019; 50:e344–e418 doi: 10.1161/STR.0000000000000211.

[1142] Sandercock PA, Counsell C, Tseng MC, Cecconi E. Oral antiplatelet therapy for acute ischaemic stroke. Cochrane Database Syst Rev. 2014:CD000029. doi: 10.1002/14651858.CD000029.pub3.

concerns, we are not finalizing our proposal to remove this measure.

Comment: A few commenters expressed concern about the proposed removal timeline. A commenter recommended a 1-year prospective schedule of measures contemplated for removal, and a commenter recommended a measure removal date prior to the CY 2024 reporting period.

Response: We appreciate commenters' suggestions and will take them into consideration as we continually refine the measure sets for our quality programs. We note that after consideration of stakeholder concerns, we are not finalizing our proposal to remove this measure.

Comment: A commenter did not support our proposal to remove STK–03 because of their belief that this removal would magnify racial inequities in prescription and treatment that non-white stroke patients face.

Response: We appreciate the commenter's concern related to racial disparities. As noted earlier, we are focused on and committed to closing the health equity gap as seen in the Health Equity RFI in the proposed rule (86 FR 25554 through 25561) and in section IX.B of this final rule. We wish to clarify that STK–03 is not stratified by race which limits the ability of the measure to directly capture or address racial disparities. However, we note that after consideration of stakeholder concerns, we are not finalizing our proposal to remove this measure.

Comment: Several commenters did not support our proposal to remove STK–03 because they believed that removing it would decrease the number of available eCQMs for hospitals to choose from and discounts the investment of resources hospitals must expend to operationalize an eCQM.

Response: As discussed earlier, after consideration of stakeholder concerns, we are not finalizing our proposal to remove this measure. We note that we are finalizing our proposal to adopt two additional eCQMs and refer readers to sections IX.C.5.d.1. and IX.C.5.d.2. for more detail on our finalized proposals to adopt the Hospital Harm-Severe Hypoglycemia eCQM and Hospital Harm—Severe Hyperglycemia eCQM. Furthermore, we reiterate that we intend to introduce additional eCQMs into the program as ones that support our evolving program goals become available.

After consideration of the public comments we received, we are not finalizing our proposal to remove the Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03) eCQM. We thank the commenters for their comments and suggestions, which we will take into consideration when assessing what changes, if any, should be incorporated into this important measure for the future.

(b) Discharged on Statin Medication (STK–06)

Comment: Many commenters expressed support for our proposal to remove the STK–06 eCQM from Hospital IQR Program measure set. Several commenters stated the proposal would reduce unnecessary administrative and reporting burden and expressed appreciation for CMS' efforts to continually review the measure set and balance the core set of eCQMs reported to CMS.

Response: We thank commenters for their support of the proposal to remove STK–06 from the Hospital IQR Program.

Comment: A few commenters did not support our proposal to remove the STK–06 measure due to concern that small hospitals lack other eCQMs to report based upon their patient population.

Response: We acknowledge that facilitating quality improvement for small hospitals can present unique challenges. We direct readers to section IX.C.5.d. where we are finalizing our proposal to adopt the Hospital Harm-Severe Hyperglycemia eCQM and the Hospital Harm-Severe Hypoglycemia eCQM into the Hospital IQR Program measures set in part because it would expand the number of eCQMs available for reporting. We also acknowledge that there are situations in which a hospital may have few or zero patients that meet the denominator criteria of a particular eCQM (79 FR 50323 through 50324). We remind readers of the Hospital IQR Program's zero denominator declaration and case threshold exemption policies, finalized in the FY 2016 IPPS/LTCH PPS final rule. Utilization of a zero denominator declaration and case threshold exemption are considered as part of the criteria for successful submissions when reporting eCQMs for the Hospital IQR Program (80 FR 49695). We later clarified that hospitals are permitted to enter a value of zero to demonstrate that they had no clinical cases (81 FR 57153). We also refer readers to section IX.C.9.e.3. of this final rule for our zero denominator declaration and case threshold exemption policy, which states hospitals can continue to meet the reporting requirements by submitting data via zero denominator declaration or case threshold exemption (82 FR 38387). It remains our goal to expand EHR-based quality reporting in the Hospital IQR Program, which we believe will ultimately provide more flexibility for hospitals to choose measures that are most representative of their patient populations.

Comment: A commenter did not support our proposal due to the investment of time and resources previously incurred to implement the measure.

Response: We acknowledge the time, effort, and resources that hospitals expend on implementing eCQMs. As discussed in the proposed rule, we believe that costs are multifaceted and include the burden associated with reporting as well as costs related to program implementation and maintenance, which are applicable both to providers and CMS (83 FR 41540). Removing STK–06 under Factor 8 will eliminate costs associated with implementing and maintaining these measures for the Hospital IQR Program. For healthcare providers, the costs associated with STK–06 include maintaining the general administrative knowledge needed to report these measures as well as the costs associated with implementing and maintaining measure specifications in hospitals' EHR systems for all the eCQMs available for use in the Hospital IQR Program (83 FR 41568). We also recognize that CMS expends resources when maintaining information collection systems and analyzing reported data. Removing these measures will reduce provider and program costs alike. In summary, removing STK–06 will reduce the costs associated with them in the Hospital IQR Program while still maintaining an efficient measure set that continues to effectively promote quality care. Removing STK–06 supports using a parsimonious set of the most meaningful measures available to track patient outcomes and impact, in keeping with the Meaningful Measures Framework (83 FR 41567). Maintaining an unnecessarily large or complicated measure set including measures that are not meaningful to consumers and caregivers hampers the Hospital IQR Program's effectiveness (83 FR 41544).

Comment: A few commenters expressed concern about the date proposed for measure removal. A commenter recommended a one-year prospective schedule of measures contemplated for removal, and a commenter recommended the removal of the STK–06 measure removal date prior to the CY 2024 reporting period.

Response: We establish program requirements considering all hospitals that participate in the Hospital IQR Program at a national level, which involves a wide spectrum of capabilities and resources with respect to eCQM

reporting. In establishing our eCQM policies, we must balance the needs of hospitals with variable preferences and capabilities. We recognize that some hospitals and health IT vendors may prefer earlier removal in order to forgo maintenance on those eCQMs proposed for removal (83 FR 41569). We believe our proposal would spare hospitals that have already allocated and expended resources in preparation for the CY 2023 reporting period. We developed our proposal to remove STK–06 from the eCQM measure set beginning with the CY 2024 reporting period/FY 2026 payment determination in response to stakeholder feedback for more time to prepare for changes to eCQM reporting requirements, including changes to the eCQM measure set (83 FR 41573).

Comment: A few commenters opposed removal of STK–06 due to concern that removal of the measure does not align with current clinical guidelines and recommended measure modification to improve the measure's utility.

Response: We acknowledge the commenters' perspective but disagree and believe the 2019 updated American Heart Association/American Stroke Association stroke guidelines on antiplatelet treatment indicate that STK–06 is not the most suitable measure for improving patient outcomes in stroke treatment during the acute period. As stated in the proposed rule (86 FR 25581 through 25582) we found that the updated 2019 American Heart Associations (AHA)/American Stroke Association (ASA) stroke guidelines on antiplatelet treatment indicate that STK–06 is not the most suitable measure for improving patient outcomes in stroke treatment during the acute period.[1143] [1144] We believe the body of evidence supporting the benefits of retaining STK–06 has been weakened by the findings of the AHA/ASA stroke guidelines. This is because the strongest recommendations and quality of evidence are for administration of aspirin in patients with Acute Ischemic Stroke within 24 to 48 hours after onset. Furthermore, there is only moderate quality evidence to continue STK–06, the measure of ischemic stroke patients who are prescribed or continue to take statin medication at hospital discharge.[1145] [1146] Lastly, other measures like STK–02, Discharged on Antithrombotic Therapy, and STK–05, Antithrombotic Therapy by The End of Hospital Day 2, already support our efforts to improve care and patient outcomes in the acute period. Taken together we believe that the benefit of retaining STK–06 has been reduced. Given these reduced benefits, we believe that the costs associated with this measure outweigh the benefits of retaining this measure in the Hospital IQR Program measure set. In order to move the program forward in the least burdensome manner while maintaining a parsimonious set of the most meaningful quality measures, we believe it is appropriate to remove the STK–06 eCQM. We do not have plans to modify the measure specifications at this point, but we appreciate commenters' suggestions and will take them into consideration.

Comment: A commenter expressed concern about possible reporting burden if there is misalignment of eCQM measure options for hospitals reporting to CMS and The Joint Commission.

Response: We acknowledge the comment and recognize that changing our measure set may cause the Hospital IQR Program to fall out of alignment with measure sets of other reporting systems. We seek to align efforts, but the Hospital IQR Program is separate and distinct from The Joint Commission. While we intend to continue to consider other quality monitoring organizations' requirements in building our own measure set, the decision to remove measures from the Hospital IQR Program is an extension of our goal under the Meaningful Measures Framework to continually refine the Program's measure set so as to use a parsimonious set of the most meaningful measures.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

7. Summary of Previously Finalized and New Hospital IQR Program Measures

a. Summary of Previously Finalized and New Hospital IQR Program Measures for the FY 2023 Payment Determination

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2023 Payment Determination:

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[1143] Kennedy J, Hill MD, Ryckborst KJ, Eliasziw M, Demchuk AM, Buchan AM; FASTER Investigators. Fast Assessment of Stroke and Transient Ischaemic Attack to Prevent Early Recurrence (FASTER): a randomised controlled pilot trial. Lancet Neurol. 2007; 6:961–969. doi:10.1016/S1474–4422(07)70250–8.

[1144] Yoshimura S, Uchida K, Daimon T, Takashima R, Kimura K, Morimoto T; on behalf of the ASSORT Trial Investigator. Randomized controlled trial of early versus delayed statin therapy in patients with acute ischemic stroke: ASSORT Trial (Administration of Statin on Acute Ischemic Stroke Patient). Stroke. 2017;48:3057–3063. doi:10.1161/STROKEAHA.117.017623.

[1145] Powers WJ, Rabinstein AA, Ackerson T, Adeoye OM, Bambakidis NC, Becker K, Biller J, Brown M, Demaerschalk BM, Hoh B, Jauch EC, Kidwell CS, Leslie-Mazwi TM, Ovbiagele B, Scott PA, Sheth KN, Southerland AM, Summers DV, Tirschwell DL; on behalf of the American Heart Association Stroke Council. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2019; 50:e344–e418 doi: 10.1161/STR.0000000000000211.

[1146] Sandercock PA, Counsell C, Tseng MC, Cecconi E. Oral antiplatelet therapy for acute ischaemic stroke. Cochrane Database Syst Rev. 2014:CD000029. doi: 10.1002/14651858.CD000029.pub3.

Measures for the FY 2024 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Claims and Electronic Data Measures		
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity***	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids****	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* The COVID-19 Vaccination Coverage Among Health Care Personnel measure is being finalized for adoption in this final rule. We refer readers to section IX.C.5.c. of the preamble of this final rule for more detail.

** In the FY 2020 IPPS/LTCH PPS final rule, we finalized our proposal to remove the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and to replace it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** The Maternal Morbidity structural measure is being finalized for adoption in this final rule. We refer readers to section IX.C.5.a. of the preamble of this final rule for more detail.

**** Finalized in the FY 2020 IPPS/LTCH PPS final rule to add Safe Use of Opioids – Concurrent Prescribing to the eCQM measure set, beginning with the CY 2021 reporting period/FY 2023 payment determination with a clarification and update (84 FR 42449 through 42459).

b. Summary of Previously Finalized and New Hospital IQR Program Measures for the FY 2024 Payment Determination

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2024 Payment Determination and Subsequent Years:

Measures for the FY 2024 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Claims and Electronic Data Measures		
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity***	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids****	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* The COVID-19 Vaccination Coverage Among Health Care Personnel measure is being finalized for adoption in this final rule. We refer readers to section IX.C.5.c. of the preamble of this final rule for more detail.

** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** The Maternal Morbidity Structural Measure is being finalized for adoption in this year's final rule. We refer readers to section IX.C.5.a. of the preamble of this final rule for more detail.

**** Reporting on the Safe Use of Opioids – Concurrent Prescribing eCQM is mandatory for the FY 2024 payment determination and subsequent years. We note that in the CY 2022 OPPS/ASC proposed rule, we request information from stakeholders on this measure.

c. Summary of Previously Finalized and New Hospital IQR Program Measures for the FY 2025 Payment Determination

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2025 payment determination:

Measures for the FY 2025 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Claims and Electronic Data Measures		
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Hybrid HWM***	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity****	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids*****	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01******	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02******	Hospital Harm—Severe Hyperglycemia Measure	3533e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* The COVID-19 Vaccination Coverage Among Health Care Personnel measure is being finalized for adoption in this final rule. We refer readers to section IX.C.5.c. of the preamble of this final rule for more detail.

** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** In this final rule, we are finalizing adoption of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.

**** The Maternal Morbidity Structural Measure is being finalized for adoption in this final rule. We refer readers to section IX.C.5.a. of the preamble of this final rule for more detail.

***** Reporting on the Safe Use of Opioids measure is mandatory for the FY 2024 payment determination and subsequent years. We note that in the CY 2022 OPPS/ASC proposed rule, we request information from stakeholders on this measure.

****** The Hospital Harm-Severe Hypoglycemia Measure and the Hospital Harm-Severe Hyperglycemia Measure are being finalized for adoption in this final rule. We refer readers to sections IX.C.5.d.1. and IX.C.5.d.2. of the preamble of this final rule for more detail.

d. Summary of Previously Finalized and New Hospital IQR Program Measures for the FY 2026 Payment Determination

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2026 payment determination:

Measures for the FY 2026 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Claims and Electronic Data Measures		
Hybrid HWM**	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	N/A
Hybrid HWR***	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity****	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
Safe Use of Opioids *****	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01 ******	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02 ******	Hospital Harm—Severe Hyperglycemia Measure	3533e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* The COVID-19 Vaccination Coverage Among Health Care Personnel measure is being proposed for adoption in this final rule. We refer readers to section IX.C.5.c. of the preamble of this final rule for more detail.

** In this final rule, we finalized the adoption of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.

*** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

**** The Maternal Morbidity Structural Measure is being finalized for adoption in this final rule. We refer readers to section IX.C.5.a. of the preamble of this final rule for more detail.

***** Reporting on the Safe Use of Opioids measure is mandatory for the FY 2024 payment determination and subsequent years. We note that in the CY 2022 OPPS/ASC proposed rule, we request information from stakeholders on this measure.

****** The Hospital Harm-Severe Hypoglycemia Measure and the Hospital Harm-Severe Hyperglycemia Measure are being finalized for adoption in this final rule. We refer readers to sections IX.C.5.d.1. and IX.C.5.d.2. of the preamble of this final rule for more detail.

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8. Future Considerations

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality and cost improvements through the inpatient hospital setting. Additionally, the emergence of COVID–19 has highlighted various impacts on measure outcomes and care of patients, which we believe are important to address. We have identified potential future measures or topics for future development, which we believe address areas that are important to stakeholders, but which are not currently covered in the Hospital IQR Program measure set. Therefore, we sought stakeholder feedback on potential new measures and future considerations for the Hospital IQR Program. These are discussed in more detail later in this section.

a. Potential Future Development and Inclusion of a 30-Day, All-Cause Mortality Measure for Patients Admitted With COVID–19 Infection

We are working to learn more about the impact of the COVID–19 infection on measure outcomes, particularly readmission and mortality measures, and about how the burden of the PHE for COVID–19 influences hospitals' ability to care for patients. To support our efforts, we are considering the potential future inclusion of a new hospital-level measure of all-cause mortality for Medicare beneficiaries admitted with COVID–19 infection (COVID–19 mortality measure). Such a measure would likely be similar to other hospital-level mortality measures currently in use in CMS programs, such as the AMI and Heart Failure 30-day mortality measures adopted for the Hospital IQR Program in the CY 2007 OPPS/ASC final rule (71 FR 68201) and the Pneumonia 30-day mortality measure adopted for the Hospital IQR Program in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47346 through 47351). These measures were later adopted for HVBP in the FY 2011 Hospital VBP final rule (76 FR 26497 through 26511). For example, the measure would likely be constructed with the measure cohort including patients admitted with COVID–19 based on principal or in select cases based on secondary diagnoses, the outcome being mortality within a specified number of days from admission (such as 30 days), and risk adjustment based on clinical factors and constructed using hierarchical modelling. The measure would use administrative claims data; however, development and reporting data would not include the January 1, 2020 through June 30, 2020 data excluded in the blanket ECE issued in response to the PHE for COVID–19.

Public reporting of this measure would not be feasible until at least FY 2023 due to the time required for measure development, testing, and production, as well as statutorily required pre-rulemaking (inclusion on the Measures Under Consideration list for public comment and review by the MAP) and notice and comment rulemaking. To inform our measure development, we sought public comment in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25588) on the potential future inclusion of a COVID–19 mortality measure in the Hospital IQR Program. Specifically, we sought input on:

- The timeline and approach for implementing a COVID–19 mortality measure. We seek stakeholder comment on balancing the priority of obtaining rapid information to improve quality of care for patients during the COVID–19 pandemic with the potential benefits of a phased approach to implementation, that might include, for example, a dry run, voluntary reporting, and/or confidential reporting prior to public reporting on the *Care Compare* website;
- The population (type of patients) to include in the COVID–19 mortality measure cohort. Specifically, diagnosis codes for principal diagnosis of COVID–19, and other key diagnoses, such as pneumonia or sepsis, if COVID–19 is coded as a secondary diagnosis present on admission;
- The potential inclusion of both Medicare FFS beneficiaries and Medicare Advantage patients, as feasible;
- Risk factors we should consider adjusting for in the measure, such as clinical risk factors or comorbidities available in administrative claims data; and
- The potential stratification of measure results, as feasible, such as by social risk factors, geographic location, and/or prevalence or burden of COVID–19 disease, and how to define these characteristics.

We received comments on this topic.

Comment: Several commenters supported the future development of a COVID–19 mortality measure. Commenters agreed with the proposed approach of initially having the COVID–19 mortality measure be confidentially reported.

Response: We thank commenters for their support of the potential inclusion of a COVID–19 mortality measure into the Hospital IQR Program measure set. We will continue to seek stakeholder input if this measure moves forward with development.

Comment: Several commenters shared concerns regarding potential specifications for such a measure, particularly the cohort overlap and potential for risk adjustment. Many commenters stated that further research is needed to understand COVID–19's relationship to existing condition-specific and proposed measures. Specifically, a few commenters indicated that the cohort captured in a COVID–19 morality measure could potentially overlap with the Hybrid HWM measure cohort, making the development of a COVID–19 mortality measure redundant. Further, they noted that the development of a COVID–19 mortality measure is reactionary to the current pandemic and that there is no universally agreed upon standard of care for COVID–19 patients. Additionally, commenters stated that it may not be worth the time and resources to develop a COVID–19 mortality measure given the decline in COVID–19-related deaths. Some commenters disagreed with the development of a COVID–19 mortality measure expressing concerns regarding sufficient model risk-adjustment. These commenters were concerned about the ability to adopt a risk-adjustment methodology that would account for various underlying factors that attributed to being at high-risk for COVID–19 infection and the need for risk-adjustment and stratification methodologies to be adequately tested.

Response: We thank the commenters for their feedback. We agree that the rapidly evolving nature of the COVID–19 PHE presents unique challenges to measurement. However, given the significant impact of COVID–19 on patients and hospitals, we also believe it is critical to measure the impact of COVID–19 on quality outcomes in order to provide information necessary to improve the quality of care for patients. We will continue to analyze additional COVID–19 data as it becomes available to better understand the relationship between COVID–19 and outcomes such as mortality.

Comment: A few commenters recommended that a potential future COVID–19 mortality measure be fully vetted and endorsed by the National Quality Forum (NQF) before inclusion into the Hospital IQR Program.

Response: We thank commenters for their recommendation.

We will continue to analyze additional data as it becomes available. Any future proposal to implement such a measure would be announced through notice and comment rulemaking.

b. Potential Future Inclusion of a Hospital-Level, Risk Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty

(1) Background

Approximately 6 million adults aged 65 or older suffer from osteoarthritis in the U.S.[1147] Osteoarthritis accounts for more than half of all arthritis-related hospitalizations,[1148] and in 2013 there were approximately 1,023,000 hospitalizations for osteoarthritis.[1149] Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,[1150] and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.[1151] Elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.[1152] THA and TKA offer significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.[1153 1154 1155 1156] However, not all patients experience benefit from these procedures.[1157] Many patients note that their preoperative expectations for functional improvement have not been met.[1158 1159 1160 1161] In addition, clinical practice variation has been well documented in the U.S.,[1162 1163 1164] readmission and complication rates vary across hospitals,[1165 1166] and international experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.[1167] For example, data from the United Kingdom demonstrates that there is a greater than 15 percent difference across hospitals in the proportion of patients showing improvement after surgery.[1168 1169]

Peri-operative care and care coordination across provider groups and specialties have important effects on clinical outcomes.[1170 1171] The goal of a hospital-level outcome measure is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patients' health and reducing the burden of their disease. THA and TKA procedures provide a suitable environment for optimizing care, as there are many studies indicating how hospitals and providers can improve outcomes of their patients by addressing aspects of pre-, peri-, and postoperative care.[1172 1173 1174 1175 1176 1177]

Due to the absence of large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, in November 2015 CMS established an incentivized, voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model to support measure development. Requirements for successful submission of PRO data for eligible elective primary THA/TKA procedures were identified by CMS in the 2015 CJR final rule (80 FR 73274).

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This Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty performance measure (THA/TKA) (THA/TKA PRO–PM) was developed and tested using PRO and risk variable data collected from and submitted by CJR participant hospitals. PRO data from the first few performance years for the CJR model revealed hospital-level variation in these outcomes across U.S. hospitals, although the full degree and extent of variation is unknown.

In October 2017, we launched the Meaningful Measures Framework to identify high priority areas for quality measurement that improve patient outcomes while also reducing burden on providers.[1178] The initiative captures the agency's vision in evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The scope of the Meaningful Measures Framework continues to evolve as the health care environment continues to change. Meaningful Measures 2.0 is currently underway and aims to promote better collection and integration of patients' voices by incorporating PRO measures that are embedded into the clinical workflow, are easy to use, and reduce reporting burden.[1179] The THA/TKA PRO–PM is fully developed aligns with these Meaningful Measures 2.0 goals.

Elective THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be measured in a scientifically sound way,[1180] [1181] [1182] [1183] [1184] [1185] [1186] [1187] [1188] [1189] [1190] [1191] [1192] are influenced by a range of improvements in care,[1193] [1194] [1195] [1196] [1197] [1198] [1199] [1200] and demonstrate hospital-level variation even after patient case mix adjustment.[1201] [1202] Further, THA/TKA procedures are specifically intended to improve function and reduce pain, making PROs a meaningful outcome metric to assess.[1203]

(2) Overview of Measure

The THA/TKA PRO–PM reports the hospital-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older.

Substantial clinical improvement would be measured by achieving a pre-defined improvement in score on joint-specific PRO instruments, measuring hip or knee pain and functioning, from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery). For additional details regarding the measure specifications, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology*).

Several stakeholder groups were engaged throughout the development process of the THA/TKA PRO–PM, as required in the Measures Management System (MMS) Blueprint,[1204] including a Technical Advisory Group (TAG), a Patient Working Group, and a national, multi-stakeholder Technical Expert Panel (TEP) consisting of a diverse set of stakeholders, including providers and patients. These groups were convened by the measure developer under contract with CMS and who provided feedback on the measure concept,

[1178] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

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outcome, cohort, risk model variables, reporting results, and data collection. We also received multiple public comments used to support the development of this measure in the 2015 CJR final rule (80 FR 73274).

The THA/TKA PRO–PM (MUC20–0003) was included in the publicly available ''2020 Measures Under Consideration List.'' [1205] The MAP supported the measure, as referenced in the 2020–2021 Final Recommendations report to HHS and CMS.[1206] This measure was submitted for NQF review in March 2020.[1207] In November 2020, the NQF endorsed the THA/TKA PRO–PM (NQF #3559).

(3) Data Sources

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. The measure uses PRO and limited patient-level risk factor data collected by hospitals preoperatively and postoperatively. The measure includes two joint-specific PRO instruments—the Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. Additionally, hospitals submit either the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global or the Veterans RAND 12-Item Health Survey (VR–12), from which Mental Health subscale preoperative scores and used for risk adjustment. Claims data are used to identify eligible elective primary THA/TKA procedures for the measure cohort and additional variables for risk adjustment and accounting for response bias, including patient demographics and clinical comorbidities up to 12 months prior to surgery. The Medicare's Enrollment Database (EDB) identifies Medicare FFS enrollment and race, and the Master Beneficiary Summary File allows for determination of dual eligibility status. Demographic information from the U.S. Census Bureau's American Community Survey [1208] allows for derivation of the Agency for Healthcare Research and Quality (AHRQ) socioeconomic status (SES) index score.

(4) Outcome

In response to extensive feedback from orthopedic experts to capture PRO data for the many patients whose ''12-month'' postoperative appointments actually occur in months 10 to 14 (300 to 425 days) following surgery, the THA/TKA PRO–PM was modified slightly to reflect a longer postoperative assessment period. Specifically, the postoperative assessment period was extended from 270 to 365 days in initial development to 300 to 425 days.

The measure outcome (numerator) is the risk-standardized proportion of patients undergoing elective primary THA/TKA who meet or exceed a substantial clinical improvement threshold between preoperative and postoperative assessments on two joint-specific PRO instruments. The measure outcome will assess patient improvement in PROs using the HOOS, JR following elective primary THA and the KOOS, JR following elective primary TKA. PRO data will be collected 90 to zero days prior to surgery and 300 to 425 days following surgery. These PRO collection periods align with typical patient visits prior to and following surgery.

The measure outcome defines patient improvement as a binary outcome (''Yes''/''No'') of meeting or exceeding the pre-defined improvement threshold between preoperative and postoperative assessments on the joint-specific PRO instruments: Specifically, for THA patients, meeting or exceeding the threshold of 22 points on the HOOS, JR and, for TKA patients, meeting or exceeding the threshold of 20 points on the KOOS, JR.

(5) Cohort

The measure cohort (denominator) is Medicare FFS beneficiaries aged 65 years and older undergoing elective primary THA/TKA procedures as inpatients in acute care hospitals. We are aware that elective primary THA/TKA procedures are increasingly occurring in hospital outpatient and ambulatory surgical center settings and we are evaluating options to address measurement of those procedures and settings.

(6) Inclusion and Exclusion Criteria

The THA/TKA PRO–PM includes patients who are—

- Enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of the index admission and enrolled in Part A during the index admission;
- Aged 65 or older; and
- Discharged alive from non-Federal short-term acute care hospital.

The measure includes only elective primary THA/TKA procedures (patients with fractures and revisions are not included).

The measure excludes patients with staged procedures, defined as more than one elective primary THA or TKA performed on the same patient during distinct hospitalizations during the measurement period.

(7) Risk Adjustment

The risk model was developed with clinically relevant risk variables identified by public comment in the 2015 CJR final rule (80 FR 73274), the TEP, and expert orthopedic consultants and supported by empirical analyses, and includes risk variables collected with PRO data by hospitals in the CJR model. The preoperative score of the Mental Health subscale from two global PRO instruments (the PROMIS-Global or the VR–12) collected with CJR PRO data is included as a risk variable. In addition, the risk model includes a validated, one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, since poorly or incompletely collected PRO data may be asymmetrically distributed across lower socioeconomic or disadvantaged populations and thus potentially affect measure scores, the measure developer used empirical analyses and stakeholder input to develop an approach to account for response bias in the measure calculation. The approach uses comorbidities and social risk factors—including non-White race, dual eligibility, and AHRQ SES index lowest quartile—to predict response to the PRO survey. Weighting the responders based on their likelihood of response (given their patient characteristics) helps reduce non-response bias when calculating the RSIR.

For additional details regarding the approach to risk adjustment and the full risk model, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report), available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*).

[1205] 2020 Measures Under Consideration List. Available at *https://www.cms.gov/media/492911.*

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(8) Measure Calculation

The hospital-level THA/TKA PRO–PM measure result is calculated by aggregating all patient-level results across the hospital. At the hospital level, this measure would be calculated and presented as a RSIR, producing a performance measure per hospital which accounts for patient case mix, addresses potential non-response bias, and represents a measure of quality of care following primary elective THA and TKA. Response rates for PRO data for this measure would be calculated as the percentage of elective primary THA or TKA procedures for which complete and matched preoperative and postoperative PRO data have been submitted divided by the total number of eligible THA or TKA procedures performed at each hospital and may be reported with measure results for transparency.

As described in section IX.C.8.b.(7). of the preamble of this final rule, the measure developer under contract with CMS convened several stakeholder groups, including providers and patients, throughout measure development. Providers noted that there was a need for sufficient time and resources for initial set up and resources needed to collect data either internally or externally. As a result, we are considering a phased implementation approach for this measure. For example, similar to other novel measures recently adopted, such as the Hybrid HWR measure finalized for inclusion in the Hospital IQR Program in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465), we are considering first allowing hospitals to submit their data voluntarily before it would become mandatory for reporting as part of the Hospital IQR Program.

We are considering three different implementation approaches. One approach would be that hospitals collect their own data and send to CMS for measure calculation. Another approach would be that collection would occur by an external entity, such as through a vendor or CMS. Lastly, hospitals could collect their own data and send their data to a registry or other entity for storage, standardization, and submission to CMS for measure calculation.

We received feedback from patients and providers that they would like to utilize their PRO results as part of the shared decision-making process and had a desire for flexible data collection modes (telephone, paper, electronic). Patients were more willing to report data if they knew the survey was from their provider, they understood the importance and use of the survey, and they had access to their own survey responses.

Providers expressed concerns over survey fatigue, resources needed to collect data, and integration with EHRs. We understand the importance of aligning data collection and data submission efforts for hospital reporting of PRO data and providing a way for hospitals to integrate the collection into EHRs so the PRO data are available at the point of care.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25588 through 25592), we invited public comment on the possible future inclusion of the THA/TKA PRO–PM in the Hospital IQR Program.

We also invited public comment on other aspects of the measure related to future implementation. Specifically, we sought public comment on the following:

- A phased approach to implementation, including voluntary followed by mandatory reporting, and the timing/duration of such reporting periods.
- The mechanism of data collection and submission, including anticipated barriers and solutions to data collection and submission.
- The required thresholds for the quantity of data (that is, number of completed PRO instruments) hospitals should submit for voluntary and mandatory reporting.
- The application of the THA/TKA PRO–PM measure to settings such as hospital outpatient departments, ambulatory surgical centers, or hospital inpatient procedures followed by observation stays, such as through aligned PRO–PMs across the relevant measurement programs; CMS recognizes that over time, more THA and TKA procedures may be performed outside of the inpatient setting; as finalized in the CY 2021 OPPS/ASC final rule, THA and TKA procedures have been removed from CMS' inpatient only (IPO) procedure list (82 FR 59385, 84 FR 61355) and added to the ASC covered procedures list (CPL) (84 FR 61388, 85 FR 86146).

We received comments on these topics.

Comment: Many commenters expressed support for the future inclusion of the THA/TKA PRO–PM in the Hospital IQR Program. Specifically, a commenter agreed with the usefulness of a PRO–PM as it captures the full spectrum of a patient's care. A commenter noted that PRO–PMs are essential to determining if value-based payment models are measuring and incentivizing improvements in outcomes important to patients. Several commenters highlighted the importance of joint-specific PROMs to effectively assess a patient's postoperative goals, demonstrate the effectiveness of the patient care delivered, and provide insight to quality improvement barriers. A few commenters stated that PROs for THA/TKA ensures that patients are experiencing functional improvement as a result of their surgery as interpreted by the patients' themselves.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that THA/TKA PRO–PM should be at the physician level. A commenter recommended PROMs be included in other non-joint specific conditions as they are appreciated by patients and providers. A commenter noted the importance of the patient's perspective on survey timing. A commenter stated that we should consider additional exclusion criterions such as stroke, cardiac events, and dementia during the measurement window, as these conditions will negatively impact outcomes and PROM scores. A few commenters recommended we consider incentivizing THA/TKA PRO–PM data collection to increase collection rates. A commenter noted we should further analyze survey response rates. A commenter recommended we consider the potential long-term impact on patients and hospitals as more PRO–PMs are implemented. A few commenters suggested that we publicly report improvement scores on Care Compare, to encourage hospitals to demonstrate functional improvements of patients. A commenter stated that we should wait until the public health emergency is over to implement a PRO–PM in the Hospital IQR Program.

Response: We thank the commenters for their support of the THA/TKA PRO–PM and will take all recommendations and input under consideration. With regard to the comment on PROMs for non-joint specific conditions, we agree that PROMs are an important aspect of patient-centered healthcare and will continue to emphasize the patient voice as prioritized under our Meaningful Measures 2.0 Framework. Meaningful Measures 2.0 is currently underway and aims to promote better collection and integration of patients' voices by incorporating PRO measures that are embedded into the clinical workflow, are easy to use, and reduce reporting burden.[1209] Regarding survey response

[1209] *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

rates, we will continue to engage stakeholders to address response rates concerns. We will also continue to monitor the impact of the COVID–19 pandemic on potential data reporting.

Comment: Commenters expressed concern that the inclusion of the THA/TKA PRO–PM in the Hospital IQR Program could create burden at the hospital and provider level. A commenter stated that the measure would cause significant financial burden to hospitals to collect pre- and postoperative assessments. A few commenters inquired on the additional staff resources required and the impact on clinical workflows this measure will have. Several commenters requested CMS consider the data collection, reporting, and implementation burden on providers and hospitals; many cited hospitals' experience in the CJR model as evidence supporting the challenges associated with implementing PRO–PMs. A commenter also stated that the measure risk adjustment variables, in particular, create additional workload as they must be collected 0–90 days preoperatively. Several commenters noted that response rates are a challenge to applying PRO measurement in routine clinical care. A few commenters expressed concerns with survey fatigue, highlighting the impact on response rates a PRO–PM may have on other measures, such as the HCAHPS Survey, because patients have so many surveys to fill out. A commenter suggested that we release feedback on the voluntary reported measure under the CJR model before adopting it into the Hospital IQR Program's measure set.

Response: With respect to the burden imposed by potential implementation of this measure, we are carefully considering public comments and are seeking to advance patient-centered measurement with as little burden as possible to providers and patient. While PRO–PMs require providers to integrate data collection into clinical workflows, this integration provides opportunity for PROs to inform clinical decision making and benefits patients by engaging them in discussions about potential outcomes. We thank commenters for their suggestions and will take them into consideration. Further, the PROM instruments used to calculate pre- and postoperative scores for this THA/TKA PRO–PM were carefully considered, with extensive stakeholder input from clinicians, to be low burden and joint specific. The clinicians felt, and data demonstrated, that joint-specific functional status tools such as the HOOS, JR and KOOS, JR are more relevant for clinical decision making and are more responsive than PROMs that are not as specific. In addition, this measure was developed with extensive input from patients, who indicated strong support for a PRO–PM following elective primary THA and TKA. We will continue to evaluate data collection burden for the THA/TKA PRO–PM and will take this feedback into consideration as we shape future measures.

Regarding survey fatigue, we designed the measure to illuminate a patient's pain and functional status before and after a THA or TKA, which is different than other surveys such as HCAHPS that captures patient experience. With regard to the comment that the THA/TKA PRO–PM may have a reporting impact on other measures, such as HCAHPS, we anticipate a minimal impact to other measures as the THA/TKA PRO–PM's eligible population is procedure-specific which reduces the likelihood of the same patient receiving the HCAHPS and PROMs. Additionally, the THA/TKA PRO–PM preoperative assessment (90 to 0 days before surgery) and postoperative assessment (300 to 425 days following surgery) timeframe is different than HCAHPS, which is two weeks after a hospital visit.

Comment: A few commenters supported the extension of the postoperative assessment from 270–365 to 300–425 days. Commenters noted that this timeframe assesses long-term impacts of the procedure and demonstrates that we can develop and implement measures capturing quality beyond 90 days following surgery. A commenter expressed concern with collecting PRO data 300 to 425 days following surgery and recommended the postoperative data collection window be 12 to 16 weeks to increase response rates.

Response: In development of the THA/TKA PRO–PM, the measure developer conducted extensive stakeholder engagement to inform the postoperative assessment window. This timeframe allows for full recovery from both THA and TKA and increases opportunity for PRO response.

Comment: Several commenters expressed concern about the THA/TKA PRO–PM data collection and submission and offered potential solutions. Several commenters recommended CMS allow the use of Qualified Clinical Data Registries (QCDRs), such as the American Joint Replacement Registry (AJRR), as an efficient mechanism for data submission of the THA/TKA PRO–PM. Commenters also cited the benefit of utilizing registries with integrated PROM collection tools to reduce the burden for hospitals to collect PROM data. A commenter suggested to have the flexibility of either self-reporting or choosing a registry to reduce administrative burden rather than being forced to use one registry over another.

Response: We thank commenters for highlighting potential solutions for PRO data collection and submission and will consider these recommendations in planning for any potential future proposal of this measure.

Comment: Several commenters recommended we consider disadvantaged populations within the measure specifications and implementation. A commenter recommended that the response bias approach be critically evaluated to ensure consideration of language and other socioeconomic barriers that may impact survey completion and response. Another commenter suggested we consider the impact that PRO–PMs may have on vulnerable populations, including people with limited health literacy, before the measure is implemented in a CMS program. Another commenter recommended that we compare the patient characteristics, including socioeconomic demographics, between responders and non-responders and requested we consider alternate approaches to accounting for response bias. A commenter noted surprise that the non-response bias had little impact on the measure results and recommended additional analyses to empirically test whether individual hospitals results changed based on weighting for non-response bias. Another commenter recommended efforts be put into place to encourage lower socioeconomic and disadvantaged populations to complete surveys and ensure they have the ability to complete them. A commenter recommended we consider stratifying the measure results by quintiles of rates of dual eligible status, similar to the approach taken in the payment calculation of the HRRP. A few commenters noted the importance of risk adjustment in outcome measures, including PRO–PMs. A commenter specifically noted support for the continued collection of the Veterans RAND 12 Item Health Survey (VR–12) or Patient-Reported Outcomes Measurement Information System Scale—Global Health Fixed Length Short Form (PROMIS–10) as well as the other patient-reported questionnaires for back pain, other joint pain, and health literacy, as are currently collected in the component of CJR that includes voluntary PRO and risk variable data collection.[1210] A commenter

[1210] Centers for Medicare & Medicaid Services (CMS), HHS, Medicare Program; Comprehensive

recommended we consider dual eligibility in the risk model. Finally, a few commenters noted the importance of incorporation of socioeconomic factors in the risk adjustment model during in measure implementation to avoid unintended consequences, including intentionally choosing or avoiding patients based on their health status.

Response: We agree with commenters that considering the unique experience of populations with social risk factors is important. The approach used in development for potential non-response bias (inverse probability weighting) considers patient characteristics, including non-white race, dual eligibility, and the AHRQ SES index score. The AHRQ SES index score considers aspects of socioeconomic status, and is computed using US census data and considers factors including zip code, median household income, percentage of persons below the Federal poverty line, unemployment, education, property value, and percentage of persons in crowded households.[1211] Although preferred language spoken is not a variable currently included in the non-response bias approach, the potential measure includes health literacy in the risk model. We appreciate the comments regarding the importance of considering disadvantaged populations within the measure specifications and implementation and we will continue to assess the impact of social risk factors on the potential measure and response rates over time.

Regarding non-response bias and the measure results, as noted in the Measure Methodology Report,[1212] the comparison of hospital RSIRs for risk-adjusted model of SCB improvement with and without stabilized inverse probability weighting suggests that the results are not sensitive to the weighting adjustment. However, due to the high proportion of non-responders, we considered it important to account for the differences in characteristics of responders and non-responders found in the literature and empirically in the development testing data. Given non-response bias may be a factor for the THA/TKA PRO–PM due to associations with non-response including social risk and health status, we recommend continued inclusion of response bias adjustment for the potential measure results and will consider the recommended analysis in the future.

As discussed in section IX.B. of this final rule, we are committed to measuring and improving health equity and addressing social risk factors in quality measurement. Regarding dual eligibility, the measure developer, under contract to CMS, performed an additional assessment of the impact of social risk as captured by dual eligibility, the AHRQ SES Index (socioeconomic status), and non-white race, after the risk model was finalized. The addition of each of these three social risk variables provided no statistically significant change to the measure's model performance, variable coefficients, or the model outcome. These variables were not included in the present model, but the developer believes future assessment in reevaluation will be important. These social risk variables were, however, statistically significantly associated with response to PRO surveys—whether patient-reported outcomes were obtained for patients undergoing primary elective THA/TKA—and so were included in the calculation of stabilized inverse probability weights used to account for potential response bias. We will continue to assess the impact of social risk factors on this potential measure's results and response rates over time.

Comment: Several commenters supported the future inclusion of the THA/TKA PRO–PM as part of mandatory reporting in the Hospital IQR Program. Commenters expressed a desire for a phased implementation approach of voluntary prior to mandatory reporting to allow hospitals to have adequate time to incorporate PROM collection in their workflows and to integrate collection into their EHR system. A commenter mentioned that smaller facilities will need several years to coordinate the collection and reporting of the data required for this measure.

Response: We thank commenters for their support of future inclusion in the Hospital IQR Program and recommendations for a phased implementation approach. We discuss potential future inclusion of this measure now to allow more time and notice for providers to make the necessary enhancements to their clinical workflows. Any proposals regarding inclusion of the potential measure in a CMS program would be announced via notice and comment rulemaking.

Comment: A few commenters recommended we lower the THA/TKA PRO–PM reporting thresholds, as the 80 percent reporting threshold for the THA/TKA PROMs in the CJR payment model is too high and some hospitals are unable to meet it due to difficulty in collecting PROMs. A commenter expressed concern with gaming that can be caused through selective reporting. Another commenter recommended we consider a minimum number of cases a year that hospitals need to report.

Response: We thank commenters for their feedback. We will consider applying feedback received from these stakeholders to any future reporting of this measure.

Comment: Several commenters expressed support for the implementing the measure across different quality programs and settings. Specifically, a commenter encouraged we implement consistent PROM reporting requirements across different quality programs, including for outpatient and physician quality reporting programs. Another commenter urged swift implementation of the measure to the Hospital Value-Based Purchasing (VBP) Program. Several commenters expressed support for the expansion of the THA/TKA PRO–PM to additional care settings such as hospital outpatient departments and ambulatory surgical centers. A commenter expressed appreciation of CMS' potential application of the PRO–PM in other healthcare settings, noting that the measure should be site agnostic and include home care or outpatient physical therapy settings. A few commenters encouraged and praised CMS for their mindfulness and forward thinking in monitoring the changes in healthcare delivery settings, noting the migration of services to the ambulatory setting. A commenter noted that the expansion of this measure to other settings will allow for transparency of provider quality in this important measurement area. A few commenters suggested stratifying data based on the site of service (inpatient, outpatient and ASCs). A commenter added that additional time may be necessary for ASCs and outpatient settings to develop the policies/procedures to collect and report the data.

Response: We thank commenters for their support of expanding this measure to other programs and settings. We agree

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Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services. Final Rule With Comment Period. **Federal Register**, 2015. 80: p. 73494–73495.

[1211] Chapter 1: Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. January 2008. Agency for Healthcare Research and Quality, Rockville, MD. *http://archive.ahrq.gov/research/findings/final-reports/medicareindicators/medicareindicators1.html.*

[1212] Balestracci K, Suter LG, Lin Z, Kurkurina et al. 2021 Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure Methodology Report (Version 1.0). March 2021. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

that monitoring physician practice trends is important. We will consider these recommendations in planning for any future proposal of this measure.

We will continue to consider the public comments we received and any future stakeholder input on the potential future inclusion of the THA/TKA PRO–PM in the Hospital IQR Program. Any proposals regarding inclusion of the measure in a CMS program would be announced via notice and comment rulemaking.

c. Potential Future Efforts To Address Health Equity in the Hospital IQR Program

Significant and persistent inequities in health care outcomes exist in the United States.[1213] Inequities in the social determinants of health affecting these groups, such as poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks. Therefore, we are committed to achieving equity in health care outcomes, including by improving data collection to better measure and analyze disparities across programs and policies.[1214] Please see Closing the Health Equity Gap in CMS Quality Programs—A Request for Information, in section IX.B. of the preamble of the proposed rule, for additional information about our current disparity methods and its potential expansion.

We have also identified potential opportunities specific to the Hospital IQR Program where we could leverage current measures or develop new measures to address the gap in existing health inequities. These opportunities include the stratification of HWR measure data by both dual eligibility and race and ethnicity, and the inclusion of a structural measure assessing the degree of hospital leadership engagement in health equity performance data.

(1) Potential Future Confidential Stratified Reporting for the Hospital-Wide All-Cause Unplanned Readmission Measure Using Both Dual Eligibility and Race/Ethnicity

(a) Background

As described in section IX.B. of the preamble of this final rule, where we discuss Closing the Health Equity Gap in CMS Hospital Quality Programs—A Request for Information, we currently provide hospitals with confidential, hospital-specific reports (HSRs) containing performance results of six condition-specific readmission measures stratified by dual-eligibility status (82 FR 41589, 84 FR 42497 through 42500).

(b) Potential Future Expansion of Hospital-Wide All-Cause Unplanned Readmission (HWR) Measure Data and Stratification

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25592), we sought comment on potentially expanding our efforts to provide results of the Within- and Across-Hospital Disparity Methods to promote health equity and improve healthcare quality. Specifically, we sought comment on the idea of stratifying the performance results of the Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) by dual eligibility and indirectly estimated race and ethnicity, as described in section IX.B. of the preamble of this final rule. We also sought comment on the idea of stratifying said performance results by disability status and seek suggestions for appropriate measures of disability status that could be derived from administrative data or self-reporting for this purpose. Results would be presented if technically feasible, adequately representative, and statistically reliable.

We believe that concurrently reporting equity results for the HWR claims-only measure in addition to the six condition-specific measures already stratified by dual eligibility would be advantageous as the measures often provide complimentary insights about different dimensions of hospital quality.[1215] In addition, the HWR claims-only measure includes a larger patient population, allowing hospitals that may be too small to have meaningful results for condition-specific measures to receive stratified results for the HWR claims-only measure. Stratification of the HWR claims-only measure, by both dual eligibility, indirectly estimated race and ethnicity, and potentially by disability status would provide additional information regarding disparities measured within individual hospitals and across hospitals nationally.

We are considering an incremental approach to public reporting, first providing the HWR claims-only measure stratification results (by both dual eligibility and race/ethnicity) in confidential HSRs. This approach would allow stakeholders an opportunity to become more familiar with, and gain comfort with, interpreting stratified results for the HWR claims-only measure using both dual eligibility and indirect estimation of race and ethnicity, prior to anticipated future public reporting of stratified measure data. Any proposal to display stratified quality measure data for any measures on the *Care Compare* website, or expand stratified reporting to additional social risk factors, would be made through future rulemaking. We anticipate being able to provide the data in the HSRs in spring 2022. We intend to consider feedback on potential disability status stratification for future updates of these measures.

We invited public comment on the following:

- The possibility of confidentially reporting in HSRs stratified results using indirectly estimated race and ethnicity, dual eligibility status and potentially by disability status, for the Hospital-wide Readmission claims-only measure, using both methods (within and across hospitals).
- The possibility of publicly reporting stratified results using indirectly estimated race and ethnicity, dual eligibility and potentially by disability status, publicly on *Care Compare,* after at least one year of confidential reporting for the Hospital-Wide Readmission claims-only measure.

(2) Potential Future Reporting of a Structural Measure To Assess the Degree of Hospital Leadership Engagement in Health Equity Performance Data

To ensure that all Medicare patients receive excellent care, regardless of individual characteristics, such as dual eligibility status, race, ethnicity, and disability status, we believe that organizational leadership and culture can play an essential role in advancing equity goals. The Agency for Healthcare Research and Quality (AHRQ) [1216] and The Joint Commission (TJC) [1217] have

[1213] United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.*

[1214] Centers for Medicare Services. *CMS Quality Strategy.* (2016). *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[1215] Rosen AK, Chen Q, Shwartz M, Pilver C, Mull HJ, Itani KF, Borzecki A. Does Use of a Hospital-wide Readmission Measure Versus Condition-specific Readmission Measures Make a Difference for Hospital Profiling and Payment Penalties? Med Care. 2016 Feb;54(2):155–61. doi: 10.1097/MLR.0000000000000455. PMID: 26595224.

[1216] Agency for Healthcare Research and Quality. Leadership Role in Improving Safety. 2019. *https://psnet.ahrq.gov/primer/leadership-role-improving-safety.*

[1217] The Joint Commission. Sentinel Event Alert. 2009 Aug. 27;(43):1–3 *https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/*

both published information on the important role of health care organizational leadership in setting an organizational culture of quality and safety. We are committed to supporting health care organizations in building a culture of equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. Hospital leadership can be instrumental in setting specific, measurable, attainable, relevant, and time-based goals, to assess progress towards achieving equity priorities and ensuring care is equally accessible to all individuals.

To improve public transparency, we sought comment on the potential future collection of one or more attestation-based structural measure(s), to be developed, assessing priority domains related to organizational commitment to health equity including:

- The degree to which the hospital organization regularly examines existing algorithms for the presence of bias, and regularly shares these findings with the hospital organization's leadership and board of directors;
- The presence of the hospital organizational *disparities impact statement,* along the lines of what is discussed in the CMS publication ''Building an Organizational Response to Health Disparities: Disparities Impact Statement'' [1218] which identifies and prioritizes actionable steps towards addressing health disparities;
- The presence of an updated *language access plan,*[1219] as defined by the CMS Office of Minority Health, to competently care for individuals with limited English proficiency;
- The presence of an updated *communication access plan,*[1220] as described by the CMS Office of Minority Health, to competently care for individuals who have visual or sensory disabilities;
- The degree to which the hospital's electronic health record system has capabilities to collect demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, and disability status) in alignment with national data collection [1221] and interoperable exchange standards; [1222] [1223] and
- The degree to which the hospital conducts staff training on best practices in collection of demographic information.

We believe these types of organizational commitment structural measure(s) would build on the current health disparities reporting, and support hospitals in quality improvement, efficient, effective use of resources, and leveraging available data. As defined by AHRQ, structural measures aim to ''give consumers a sense of a health care provider's capacity, systems, and processes to provide high-quality care.'' [1224] We acknowledge that collection of this structural measure may impose administrative and/or reporting requirements for hospitals. To allow stakeholders an opportunity to become more familiar with, and gain comfort with, components of the structural measure related to organizational commitment to health equity performance, we envision an incremental approach to required reporting, starting first with a voluntary reporting period. Any future technical specifications or plans to display results of the structural measure on *Care Compare* or successor website would be made through future rulemaking. We sought feedback from stakeholders on conceptual and measurement priorities for better illuminating organizational commitment to health equity, including review of hospital outcomes stratified by social risk factors. We also sought feedback on an appropriate measure regarding organizational commitment to health equity and accessibility for individuals with intellectual and developmental disabilities.

We received comments on these topics.

Comment: Several commenters supported the creation and dissemination of measures stratified by dual eligibility, disability, and imputed race and ethnicity. They noted that publicly reporting the Hospital-Wide Readmission (HWR) stratified by dual eligibility and race/ethnicity would provide facilities with information to target quality improvement strategies. Commenters noted that reporting stratified data publicly could have unintended consequences such as patient selection or confusion for consumers and the public. Many commenters suggested that implementation of health equity measures should be incremental and allow for confidential reporting until providers become used to the new reporting requirements, including the imputation methodology. A commenter suggested that CMS provide material and documentation to aid in the appropriate interpretation of results.

Several commenters expressed concern about the lack of accuracy and actionability of imputed data. They stated that stratified results should only be publicly available for self-reported race and ethnicity and recommended against using imputed data in reporting and payment programs. Others recommended only using indirect methods of calculating race and ethnicity for confidential reporting. Several commenters also requested more detailed information on the methodology used to impute race and ethnicity. A commenter recommended against using imputed race and ethnicity for confidential reporting.

Numerous commenters expressed concern that additional reporting requirements would negatively impact providers with increased administrative burden. Many commenters requested that CMS work closely with both providers, stakeholders, patients, and organizations such as the NQF in the development of stratified health equity measures, to ensure that such measures provide actionable insights and do not unduly burden or negatively impact providers.

Commenters also supported the collection and use of additional social risk factors such as language or LGBTQ status. A commenter recommended CMS collect data that are actionable, such as ICD–10–CM codes on social risk factors. Additionally, a commenter highlighted that several factors such as access to food, housing or transportation could impact racial and ethnic disparity results, and that collecting and accounting for such factors could allow CMS to better estimate the effect of structural racism on health disparities. Another commenter requested additional information on what CMS intends to use to measure disability status.

Response: We appreciate the feedback, recommendation and request

topics-library/sea_43pdf.pdf?db=web&hash=595C815B483DA56EDF745A94F95326F4.

[1218] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities. 2018. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.*

[1219] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities: Guide to Developing a Language Access Plan. 2018. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.* A language access plan is defined as a document that spells out how to provide services to individuals who are non-English speaking or have limited English proficiency.

[1220] Centers for Medicare and Medicaid Services. Improving Communication Access for Individuals Who Are Blind or Have Low Vision. *https://www.cms.gov/files/document/omh-visual-sensory-disabilities-brochure-508c.pdf.*

[1221] 2015 Edition Cures Update certification criteria Demographic Data. 45 CFR 170.315(a)(5).

[1222] 2015 Edition Cures Update Certification Criteria Standardized API for Patient and Population Services. 45 CFR 170.315(g)(10).

[1223] 2015 Edition Cures Update Certification Criteria United States Core Data for Interoperability (USCDI). 45 CFR 213.

[1224] Agency for Healthcare Research and Quality. Types of Health Care Quality Measures. 2015. *https://www.ahrq.gov/talkingquality/measures/types.html.*

for additional information. We will take into consideration the feedback, recommendations, and requests for additional information as we develop future plans.

Comment: While numerous commenters supported potential future reporting of health equity outcome measures specific to the Hospital IQR Program, many expressed concerns that the proposed structural measure related to organizational commitment to health equity was too broadly defined to result in meaningful or actionable data. Several commenters asked for additional clarification and specificity on how a potential health equity structural measure would be constructed. A commenter highlighted the need for a demonstrated linkage between such a measure and the improvement of patient outcomes. Some commenters expressed a preference for outcomes-based approaches to measuring health equity rather than structural concepts. They noted that outcome variables better relay the experience of patients, offer clear goals for care givers, and help hospitals better identify whether they are providing equal care than process based measures, which often focus on organizational initiatives. Others noted that a localized, focused approach unique to a hospital's specific situation is better suited to accomplish health equity.

Many commenters expressed a desire that CMS engage extensively with stakeholders in the construction of health equity reporting measures to fit reporting requirements and provide actionable data relevant to providers' needs. Another commenter suggested that CMS coordinate across government agencies to ensure that measurement and reporting requirements were standardized as much as possible to aid in data collection.

Many commenters provided feedback that additional reporting requirements would increase administrative and financial burden on providers due to necessary upgrades to reporting tools and staff training requirements.

Several commenters highlighted the need to test the health equity score structural measure to ensure feasibility and data integrity. For example, some commenters noted it is challenging to collect accurate and consistent race/ethnicity information at the time of admission to the hospital. Several commenters highlighted NQF endorsement as an important component of measure validity and reliability in the future.

Numerous commenters also supported the collection and use of additional equity-related predictor variables such as LGBTQ status, disability, housing and food insecurity status, transportation needs, and public safety. In addition, some comments highlighted other efforts currently underway to address health disparities and suggested that CMS examine currently available datasets as potential sources to develop health equity measures.

Other commenters encouraged CMS to take a measured, incremental approach in the construction and implementation of structural health equity measures in the Hospital IQR Program, on the basis that upgrades to EHRs, staff training, and the lack of standardized data collection all present barriers to quick implementation. Multiple commenters suggested that disparity measures should be confidentially reported until the measures' validity, reliability, and impact can be verified.

A commenter indicated that there were already certain accreditations and other programs that address cultural components of health equity and encouraged CMS to conduct a thorough review of current efforts underway before mandating the reporting of certain measures that would increase administrative burden. Other comments expressed doubt that the measure framework proposed by CMS was adequately supported by evidence linking it to positive clinical outcomes and improved patient experiences, and that aggregated data sets do not provide actionable or insightful data for providers. One comment argued that a decentralized method that encourages providers to develop an approach unique to their situation would yield more positive outcomes compared to a centralized approach.

Many commenters expressed overall support of CMS' goals to improve health care outcomes for Medicare beneficiaries and supported reporting HWR stratified by dual eligibility, imputed race/ethnicity, and disability to identify and understand disparities. However, other commenters expressed concern that some factors that might negatively impact a providers' performance within a health equity measure, such as geographic economic variables, were outside the providers' control.

Response: We appreciate the feedback regarding approaches for measuring organizational commitment to health equity and concerns expressed by the commenters regarding measuring health equity in our hospital quality measurement programs. We will consider the feedback, recommendations, and requests for additional information should we propose a structural measure to assess the degree of hospital leadership engagement in health equity performance data in future rulemaking.

9. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. In order to successfully participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the previous description. In accordance with the statute, the FY 2022 payment determination will begin the eighth year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

b. Maintenance of Technical Specifications for Quality Measures

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538) in which we summarized how the Hospital IQR Program maintains the technical measure specifications for quality measures and the subregulatory process for incorporation of nonsubstantive updates to the measure specifications to ensure that measures remain up-to-date. We did not propose any changes to these policies in the proposed rule.

The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.cms.gov* (or other successor CMS designated websites). The CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update) contains the technical

specifications used for electronic clinical quality measures (eCQMs). The Annual Update contains updated measure specifications for the year prior to the reporting period. For example, for the CY 2021 reporting period/FY 2023 payment determination, hospitals submitted eCQM data using the May 2020 Annual Update and any applicable addenda. Updates include code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and electronic health record (EHR) vendors. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*.

Hospitals must register and submit quality data through the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). The QualityNet Secure Portal is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E.

We also refer readers to section VIII.A. of this final rule where we requested information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard (as described in that section).

c. Procedural Requirements

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25594), we proposed to: (1) Update references to the QualityNet website, and (2) use the term ''QualityNet security official'' instead of ''QualityNet Administrator''.

(1) Updates to References to the QualityNet Website in the Hospital IQR Program Regulation Text

In November 2020, we launched a redesigned QualityNet website, and updated the URL from *QualityNet.org* to *QualityNet.cms.gov*.[1225] As a result, we proposed to update the references to this CMS resource in the Hospital IQR Program regulation text. Specifically, we proposed to remove reference to the *QualityNet.org* URL in two places:

- At 42 CFR 412.140(a)(1) by revising the sentence from ''Register on *QualityNet.org*, before it begins to report data'' to ''Register on the QualityNet website, before it begins to report data''; and
- At 42 CFR 412.140(c)(2)(i) by revising the sentence from ''Specific requirements for submission of a request for an exception are available on *QualityNet.org*'' to ''Specific requirements for submission of a request for an exception are available on the QualityNet website.''

We believe that updating the references to remove a specific URL allows for future iterations and updates to the website as technology evolves over time.

We invited public comment on our proposals to update references to the QualityNet website at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i). We received no comments on this proposal. We are finalizing our proposal as proposed.

(2) Updates to References to QualityNet Administrator

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described at 42 CFR 412.140(a)(2), 42 CFR 412.140(e)(2)(iii), and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51639 through 51640).

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25594), we proposed to use the term ''QualityNet security official'' instead of ''QualityNet Administrator'' or ''QualityNet System Administrator.'' This update in terminology would not change the individual's responsibilities or add burden, and would align with the Hospital Outpatient Quality Reporting (OQR) Program and other programs.[1226] The term ''security official'' would refer to ''the individual(s)'' who have responsibilities for security and account management requirements for a hospital's QualityNet account.

Therefore, we proposed to revise existing language at 42 CFR 412.140(a)(2) by replacing ''QualityNet Administrator'' with ''QualityNet security official.'' The revised paragraph (a)(2) will read: ''Identify and register a QualityNet security official as part of the registration process under paragraph (a)(1) of this section.''

In addition, we proposed to revise existing language at 42 CFR 412.140(e)(2)(iii) by replacing ''QualityNet system administrator'' with ''QualityNet security official.'' The revised paragraph (e)(2)(iii) will read: ''Contact information for the hospital's chief executive officer and QualityNet security official, including each individual's name, email address, telephone number, and physical mailing address.''

We invited public comment on our proposals to update references to the QualityNet security official at 42 CFR 412.140(a)(2) and 42 CFR 412.140(e)(2)(iii).

Comment: A commenter supported our proposals because it believes the updates would help simplify and streamline processes.

Response: We thank the commenter for its support.

After consideration of the public comment received, we are finalizing our proposal as proposed.

d. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. We did not propose any changes to these policies in the proposed rule.

e. Reporting and Submission Requirements for eCQMs

(1) Background

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493), FY 2019 IPPS/LTCH PPS final rule (83 FR 41567 through 41575; 83 FR 41602 through 41607), FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58940).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38368 through 38361), we

[1225] QualityNet Migration from *QualityNet.org* to *QualityNet.cms.gov*. Available at: *https://qualitynet.cms.gov/news/5fa2f7ccfa00d50025576586.*

[1226] Medicare Program; CY 2021 Medicare hospital outpatient prospective payment system. 85 FR 86182.

finalized eCQM reporting and submission requirements such that hospitals were required to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination. Those reporting requirements were extended to the CY 2019 reporting period/FY 2021 payment determination in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41603 through 41604), as well as to the CY 2020 reporting period/FY 2022 payment determination and the CY 2021 reporting period/FY 2023 payment determination in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42503).

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42503 through 42505), we finalized that for the CY 2022 reporting period/FY 2024 payment determination, hospitals would be required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (Safe Use eCQM), for a total of four eCQMs.[1227]

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a progressive increase in the number of required reported quarters of eCQM, from one self-selected quarter of data to four quarters of data over a three-year period (85 FR 58939). For the CY 2021 reporting period/FY 2023 payment determination, hospitals are required to report two self-selected calendar quarters of data for each of the four self-selected eCQMs. For the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to report three self-selected calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids eCQM. For the CY 2023 reporting period/FY 2025 payment determination and subsequent years, hospitals are required to report four calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids eCQM. We also clarified in the FY 2021 IPPS/LTCH PPS final rule that until hospitals are required to report all four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination, they may submit either consecutive or nonconsecutive self-selected quarters of data (85 FR 58939). While we did not propose any changes to these policies in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25595), we would like to clarify in case there is any confusion that beginning with the CY 2021 reporting period/FY 2023 payment determination, the self-selected eCQMs must be the same eCQMs across quarters in a given reporting year.

(2) Updates to Certification Requirements for eCQM Reporting

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 255945 through 25595), we proposed a date after which Hospital IQR Program participants must use technology certified to the 2015 Edition Cures Update and clarifying the policy that certified technology must support the reporting requirements for all available eCQMs.

(a) Requirements for the Use of Technology Certified to the 2015 Edition Cures Update Criteria Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

(i) Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41604 through 41607), we finalized a policy to require hospitals to use the 2015 Edition certification criteria for the CY 2019 reporting period/FY 2021 payment determination and subsequent years to align the Hospital IQR Program with the Medicare Promoting Interoperability Program. In May 2020, the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) updated the 2015 Edition of health IT certification criteria (''2015 Edition Cures Update''). The 2015 Edition Cures Update revises the clinical quality measurement criterion at 45 CFR 170.315(c)(3) to refer to CMS QRDA Implementation Guides (IGs) and removes the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25686). The revision was responsive to industry feedback that the health IT certified to the prior ''CQMs-report'' criterion was only or primarily being used to submit eCQMs for CMS reporting programs (85 FR 25688). These updates were finalized to reduce burden on health IT developers under the ONC Health IT certification program (85 FR 25686) and have no impact on providers' existing reporting practices for CMS programs.

The ONC 21st Century Cures Act final rule provided health IT developers up to 24 months from May 1, 2020 to make technology certified to the updated and/or new criteria available to their customers (85 FR 25670). On November 4, 2020, ONC issued an interim final rule with comment entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereafter, ''ONC interim final rule'') (85 FR 70064). In the ONC interim final rule ONC extended the compliance deadline for the update to the Clinical Quality Measures-Report criterion until December 31, 2022 (85 FR 70075). During the period until December 31, 2022, health IT developers are expected to continue supporting technology certified to the prior version of the ONC certification criteria for use by their customers (85 FR 84816).

In the CY 2021 PFS final rule (85 FR 84825 through 84828), we finalized our proposal to expand flexibility under the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and for subsequent years to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized for reporting eCQMs in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608), or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961). We adopted this flexible approach to encourage hospitals to be early implementers of the 2015 Edition Cures Update while remaining in compliance with Hospital IQR Program data submission requirements and maintaining alignment with requirements in the Medicare Promoting Interoperability Program.

(ii) Finalized Policy Regarding Use of the 2015 Edition Cures Update for eCQM Data Submission

In the proposed rule, beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years, we proposed to require hospitals to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital IQR Program data. We refer readers to the ONC 21st Century Cures Act final rule for additional information about the updates included in the 2015 Edition Cures Update (85 FR 25665).

We invited public comment on our proposal.

Comment: Several commenters supported the proposal to require use of technology certified to the 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination. Commenters recommended CMS monitor vendor and hospital progress to ensure the transition to the 2015 Edition Cures

[1227] We refer readers to the CY 2022 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule where we requested public input for potential measure updates as we prepare for NQF re-endorsement of the endorsed Safe Use of Opioids—Concurrent Prescribing eCQM and to potentially inform any future rulemaking regarding this measure.

Update remains feasible and exercise flexibility if there are health IT developer issues beyond the hospitals' control.

Response: We thank commenters for their support. We will continue to work with ONC to monitor the availability of EHR technology certified to the 2015 Edition Cures Update.

Comment: Several commenters did not support required use of the 2015 Edition Cures Update beginning with the CY 2023 reporting period citing insufficient time for hospitals to prepare and test for the requirement and concern about health IT developers' timeline to develop and deploy the technology. A few commenters recommended delaying the required use of the 2015 Edition Cures Update until the CY 2024 reporting period or the CY 2025 reporting period. Several commenters did not express support or disapproval of the proposal but recommended CMS provide adequate time for health IT developers to provide updated certified health IT to hospitals and provide more time for hospitals to operationalize and test technology updated to the 2015 Edition Cures Update for accuracy. A commenter recommended CMS continue flexibility for hospitals in the choice of certified technology required for use in CY 2023 reporting period, and a few commenters recommended CMS delay the requirement that hospitals report four calendar quarters of eCQM data for the CY 2023 reporting period in response to concerns about health IT developer readiness to meet the proposed requirement to use the 2015 Edition Cures Update by that time. A commenter recommended CMS work with ONC to issue direction to health IT developers on the deadline for delivery of complete and timely technology updated consistent with the 2015 Edition Cures Update.

Response: We appreciate commenters' concerns related to sufficient time for hospitals to prepare and test the 2015 Edition Cures Update after it is made available by their health IT developer; however, we respectfully disagree that our proposal provides insufficient time to implement. In the CY 2021 PFS final rule, we adopted a policy to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608); or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961), enabling hospitals to implement updates prior to requiring use of technology updated to the 2015 Edition Cures Update for the Hospital IQR Program. We believe our previously finalized policy allowing use of the 2015 Edition Cures Update as early as the CY 2020 reporting period provides hospitals and health IT developers flexibility and time to adjust. In combination with our proposal in this year's proposed rule, hospitals and developers have over three years to update and test systems before the February 29, 2024 submission deadline for reporting eCQM data for the CY 2023 reporting period/FY 2025 payment determination for which use of certified technology updated to the 2015 Edition Cures Update is required under our final policy. We also wish to clarify that hospitals are not required to implement certified health IT consistent with the 2015 Edition Cures Update by December 31, 2022. Rather, our requirement is that hospitals use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital IQR Program data beginning with the CY 2023 reporting period/FY 2025 payment determination.

In addition, we understand the updates to the certification criteria that ONC finalized in the ONC 21st Century Cures Act final rule do not constitute a full new Edition of technology (85 FR 25665), as the scope of updates did not warrant implementation of an entirely new Edition of certification criteria (85 FR 25664 through 25665). We understand the updates build on existing functionality and standards in technology certified to the 2015 Edition, which participants in the Hospital IQR Program have been using as part of clinical and administrative workflows since the CY 2019 reporting period/FY 2021 payment determination, if not earlier (83 FR 41604 through 41607). We note that for quality measure reporting, implementation of the 2015 Edition Cures Update will not impact hospitals' current eCQM reporting practices, and hospitals will continue to implement the required CMS annual updates (85 FR 84827). We generally update the measure specifications on an annual basis (CMS' Annual Update for the Hospital Quality Reporting Programs) to include code updates, logic corrections, non-substantive alignments with current clinical guidelines, and additional guidance for hospitals and EHR vendors to use in order to collect and submit data on eCQMs from hospital EHRs (85 FR 58932).[1228] We encourage the use of Certified Health IT Product List (CHPL) as discussed in the ONC 21st Century Cures Act final rule (85 FR 25666), which allows hospitals to identify the specific certification status of a product at any given time. We also refer readers to the impact analysis presented in the ONC 21st Century Cures Act final rule at 85 FR 25912 for more information on the impact of updating health IT products.

We acknowledge commenter's suggestion concerning collaboration with Federal partners and the availability of additional flexibility in the eCQM reporting manner and timing requirements. As stated previously, we intend to work with ONC to monitor the timely availability of EHR technology certified to the 2015 Edition Cures Update. We plan to monitor the implementation and welcome continued feedback from stakeholders through webinars, listservs, and help desk questions.

Comment: A commenter did not support required use of the 2015 Edition Cures Update beginning with the CY 2023 reporting period, citing the timeline for health IT developers to develop and make these solutions available, and hospitals to deploy updated technology, with particular concern with the pace of change and its impact on hospitals' ability to fully recover from the COVID–19 pandemic.

Response: We acknowledge these concerns and recognize the burden that the COVID–19 PHE has had on the healthcare system. If a hospital experiences an extraordinary circumstance that prevents it from reporting eCQMs, it is able to submit an individual Extraordinary Circumstances Exceptions (ECE) request form. Specifically, in the FY 2016 IPPS/LTCH PPS final rule, we finalized a policy, effective starting with the FY 2018 payment determination, to allow hospitals to utilize the existing ECE form (OMB control number 0938–1022 (expiration date December 31, 2022)) to request an exception to the Hospital IQR Program's eCQM reporting requirement for the applicable program year based on hardships preventing a hospital from electronically reporting (80 FR 49695 and 49713). We stated that such hardships could include, but are not limited to, infrastructure challenges (a hospital must demonstrate that it is in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as health IT developer issues outside of the hospital's control (including a health IT developer product losing certification (80 FR 49695 and 49713)). We assess a

[1228] The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/.*

hospital's request on an individual basis to determine if an exception is merited (80 FR 49695 and 49713). We also refer stakeholders to additional eCQM ECE resources on the QualityNet website.[1229]

Comment: Several commenters expressed concerns about product update fees passed to providers by vendors, particularly during the PHE.

Response: We understand commenters' statement about product update fees to pertain to the cost of implementing technology consistent with the 2015 Edition Cures Update. We recognize that hospitals require resources to update workflows and train staff when adopting updated certified technology. We understand and wish to highlight that the updates to the certification criteria that ONC finalized in the ONC 21st Century Cures Act final rule do not constitute a full new Edition of technology but include updates to Health IT Modules certified to existing certification criteria (85 FR 25665). We generally update the measure specifications on an annual basis (CMS' Annual Update for the Hospital Quality Reporting Programs) to include code updates, logic corrections, non-substantive alignments with current clinical guidelines, and additional guidance for hospitals and EHR vendors to use in order to collect and submit data on eCQMs from hospital EHRs (85 FR 58932).[1230]

Comment: A commenter requested we clarify whether outsourcing the eCQM functionality is allowed under this proposal.

Response: We interpret the commenter's request to mean whether Hospital IQR Program participants can use certified EHR technology from more than one health IT developer to specifically support eCQM data reporting, which is permissible. In the FY 2021 IPPS/LTCH PPS final rule, we finalized the addition of the EHR Submitter ID to the four key elements for file identification beginning with the CY 2021 reporting period/FY 2023 payment determination (85 FR 58940). An EHR Submitter ID is the ID that is assigned to submitter entities upon registering to use the HQR System (formerly referred to as the QualityNet Secure Portal) and will be used to upload QRDA I files. Particularly for situations when a hospital uses one or more vendors to submit QRDA I files via the HQR System, this additional element would prevent the risk of a previously submitted file by a different vendor unintentionally being overwritten.

Comment: A commenter recommended we permit hospitals to extract and submit data directly to CMS rather than through the service of a certified health IT developer.

Response: We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58940) for our previously adopted eCQM file format specifications, which require that hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format; (2) may use third parties to submit QRDA I files on their behalf [although not required]; and (3) may either use abstraction or pull the data from noncertified sources in order to then input these data into CEHRT for capture and reporting QRDA I files. We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505) where we state that certification criteria referenced in the 2015 Edition Base EHR definition. We refer readers to the ONC 21st Century Cures Act final rule, where the CQM report certification criterion was updated to enable users to report a data file that is formatted in accordance with the QRDA I standard (85 FR 25686 through 25690). We also highlight that we are exploring paths forward into the future of quality measures, including the use of FHIR to reduce the burden associated with quality measure reporting. We refer readers to section IX.A. for a detailed discussion of the potential use of FHIR for quality measure reporting.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

(b) Requiring EHR Technology To Be Certified to All Available eCQMs

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506), we finalized the requirement that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. We did not propose any changes to this policy in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070). We note that with the finalization in this final rule of our proposal to require hospitals to use the 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination, then all available eCQMs used in the Hospital IQR Program for the CY 2023 reporting period/FY 2025 payment determination and subsequent years would need to be reported using certified technology updated to the 2015 Edition Cures Update.

(3) File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format, (2) may use third parties to submit QRDA I files on their behalf, and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387).

More specifically regarding the use of QRDA I files, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170) and the FY 2020 IPPS/LTCH PPS final rule (85 FR 58940), in which we stated that we expect QRDA I files to reflect data for one patient per file per quarter, and identified the five key elements that are utilized to identify the file:

- CMS Certification Number (CCN);
- CMS Program Name;
- EHR Patient ID;
- Reporting period specified in the Reporting Parameters Section per the CMS Implementation Guide for the applicable reporting year, which is published on the eCQI Resource Center website at: *https://ecqi.healthit.gov/QRDA;* and
- EHR Submitter ID (beginning with the CY 2021 reporting period/FY 2023 payment determination).

We did not propose any changes to these policies in the proposed rule.

(4) Submission Deadlines for eCQM Data

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57172) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR and Medicare Promoting Interoperability Programs. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized the alignment of the Hospital IQR Program eCQM submission deadline with that of the Medicare Promoting Interoperability

[1229] See *https://www.qualitynet.org/inpatient/measures/ecqm/participation#tab2.*

[1230] The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/.*

Program—the end of two months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday. We did not propose any changes to these policies in the proposed rule.

f. Data Submission and Reporting Requirements for Hybrid Measures

In the proposed rule, we proposed that hybrid measures comply with the same certification requirements and timeline as eCQMs. This provision is in alignment with the updates, as previously discussed, for eCQMs requiring the use of certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY 2023 reporting period/CY 2025 payment determination.

(1) Background

The Hospital IQR Program recently adopted hybrid measures into the program's measure set. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized voluntary reporting of the Hybrid Hospital-Wide Readmission (HWR) measure for the CY 2018 reporting period. In the FY 2020 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid HWR measure for the Hospital IQR Program (84 FR 42465 through 42481) such that, beginning with the FY 2026 payment determination, hospitals are required to report on the Hybrid HWR measure (84 FR 42479). We also finalized several requirements related to data submission and reporting requirements for hybrid measures under the Hospital IQR Program (84 FR 42506 through 42508). We also refer readers to section VIII.C.5.b. of the preamble of this final rule for more information on the adoption of the Hybrid Hospital-Wide Mortality measure.

(2) Certification and File Format Requirements

(a) Background

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 19498 through 19499), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58941), and the CY 2021 PFS final rule (85 FR 84472) for our previously adopted policies regarding certification and file format requirements for hybrid measures in the Hospital IQR Program.

In the CY 2021 PFS final rule (85 FR 84825 through 84828), we finalized flexibility to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608) or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961, 85 FR 50271), beginning with the CY 2020 reporting period/FY 2022 payment determination and subsequent years. The Hospital IQR Program offers flexibility to meet hybrid measure submission requirements to facilitate successful reporting during a period of transition from the requirement to solely use the 2015 Edition certified technology to the requirement to solely use the 2015 Edition Update certified technology. This flexibility applies to all Hospital IQR Program measures which use EHR data elements to calculate measure rates, including eCQMs and hybrid measures.

(b) Finalized Changes to the Certification Requirements for Hybrid Measure Reporting Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25596 through 25597), to align with the health IT certification requirements for eCQM reporting, we proposed to require hospitals to use only certified technology that has been updated consistent with the 2015 Edition Cures Update to submit hybrid measure data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to our previous discussion for more detail on the finalized changes to the certification requirements for eCQMs.

We believe the 2015 Edition Cures Update will enhance interoperability and patients' access to their electronic health information, consistent with section 4006(a) of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016). Health IT developers have until December 31, 2022 (the date finalized in the ONC interim final rule) to make technology certified to the updated criteria available to their customers. After this date, only certified technology updated to the 2015 Edition Cures Update will be considered certified by ONC and could be used by health care providers to report for the Hospital IQR Program. We refer readers to section VIII.F.11.a.4. of the preamble of this final rule where the same finalized requirements are discussed for the Medicare Promoting Interoperability Program.

We invited public comment on our proposal.

Comment: Most commenters supported our proposal that, for hybrid measures, technology must be certified under the ONC Health IT Certification Program in accordance with the 2015 Edition Cures Update, as finalized in the ONC 21st Century Cures Act final rule (85 FR 25665). Commenters indicated their belief that requiring use of the 2015 Edition Cures Update will support standardization and quality measurement while also facilitating interoperability.

Response: We agree and thank the commenters for their support.

Comment: Several commenters raised potential concerns of the readiness of health IT vendors and hospitals to transition to the 2015 Edition Cures Update. Specifically, commenters are concerned with vendors being able to complete, and providers being able to adopt and implement, the changes associated with the 2015 Edition Cures Update by December 31, 2022.

Response: We appreciate the commenters' concerns. We refer readers to section IX.9.e.2.(a).(ii). where we previously responded to these similar concerns raised by commenters for eCQMs. We reiterate that hospitals are not required to implement certified health IT consistent with the 2015 Edition Cures Update by December 31, 2022. Rather, our requirement is that hospitals use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital IQR Program data beginning with the CY 2023 reporting period/FY 2025 payment determination.

Comment: A commenter expressed concern with health IT developers potentially passing the cost of the update on to clients to guarantee meeting required deadlines.

Response: We thank the commenter for sharing its concern. We refer readers to section IX.9.e.2.(a).(ii). where we previously responded to this similar concern raised by commenters for eCQMs.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

(3) Additional Submission Requirements

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42507), we finalized allowing hospitals to meet the hybrid measure reporting and submission requirements by submitting any combination of data via QRDA I files, zero denominator declarations, and/or case threshold exemptions. We also finalized applying similar zero denominator declaration and case threshold exemption policies to hybrid

measure reporting as we allow for eCQM reporting (84 FR 42507 through 42508).

We note that the ONC 21st Century Cures Act final rule revises the clinical quality measurement criterion at 45 CFR 170.315(c)(3) to refer to CMS QRDA IGs and removes the HL7® QRDA standard requirements (85 FR 25645). We encourage all hospitals and their health IT vendors to submit QRDA I files early, and to use one of the pre-submission testing tools for electronic reporting, such as submitting test files to the Hospital Quality Reporting (HQR) System, to allow additional time for testing and make sure all required data files are successfully submitted by the deadline.[1231] We did not propose any changes to these policies in the proposed rule.

(4) Submission Deadlines for Hybrid Measures

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42508), where we finalized submission deadlines for hybrid measures. We did not propose any changes to these policies in the proposed rule.

g. Sampling and Case Thresholds for Chart-Abstracted Measures

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. We did not propose any changes to these policies in the proposed rule.

h. HCAHPS Administration and Submission Requirements

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS submission requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. We did not propose any changes to these policies in the proposed rule.

i. Data Submission Requirements for Structural Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. Hospitals are required to submit information for structural measures once annually via a CMS-approved web-based data collection tool available via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting system secure portal). The data submission period for structural measures begins in April until the same submission deadline as for the fourth calendar quarter of the chart-abstracted measures with respect to the reporting period for the previous calendar year. For example, for the FY 2024 payment determination, hospitals would be required to submit the required information between April 1, 2023 and May 15, 2023, with respect to the time period of January 1, 2022 through December 31, 2022.

We refer readers to section VIII.C.5.a. of the preamble of this final rule, where we are finalizing the adoption of the Maternal Morbidity Structural Measure. For the Maternal Morbidity Structural Measure and the CY 2021 reporting period/FY 2023 payment determination only, we proposed and are finalizing a shortened reporting period from October 1, 2021 through December 31, 2021, while retaining the standard data submission period. Specifically, for the shortened reporting period hospitals will be required to submit the data between April 1, 2022 and May 16, 2022 (we note that May 15, 2022 falls on a weekend and therefore the close of this data submission period is moved to May 16, 2022).

Thereafter, as described in section VIII.C.5.a. of the preamble of this final rule, the reporting period for the Maternal Morbidity Structural Measure will run from: January 1 through December 31 on an annual basis, and that the data submission period will continue to be consistent with our current policy (beginning in April until the same submission deadline as for the fourth calendar quarter of the chart-abstracted measures with respect to the reporting period for the previous calendar year).

j. Data Submission and Reporting Requirements for CDC NHSN Measures

For details on the data submission and reporting requirements for measures reported via the CDC's National Healthcare Safety Network (NHSN), we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet website.

In addition, we refer readers to section VIII.C.5.c. of the preamble of this final rule for more detail on our finalized proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure, which requires facilities to report data on the number of HCP who have received the full regimen of a COVID–19 vaccine through the CDC's NHSN. Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf*. For this measure, we will require reporting a single vaccination count for each healthcare facility by each individual facility's CMS Certification Number (CCN). For each CMS CCN, a percentage of the HCP who received a complete course of the COVID–19 vaccination will be calculated and publicly reported on the Care Compare website, so that the public will know what percentage of the HCP have been vaccinated in each hospital.

Consistent with our adopted policies for CDC NHSN measures in the Hospital IQR Program, hospitals will report the measure through the NHSN web-based surveillance system.[1232] Specifically, hospitals will use the COVID–19 vaccination data reporting modules in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible to have worked at the facility during the self-selected week (denominator) and the number of those HCP who have received COVID–19 vaccination (numerator).

For the COVID–19 HCP Vaccination measure, we proposed that hospitals would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one self-

[1231] We recently decommissioned the Pre-Submission Validation Application (PSVA) tool within the HQR System because the system itself now performs the same functions that the PSVA tool previously did.

[1232] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet Hospital IQR Program requirements, beginning in October 2021 for the October 1, 2021 through December 31, 2021 reporting period affecting FY 2023 payment determination and continuing for each quarter in subsequent years. If a hospital submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. We proposed that for each quarter, the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. CMS will publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

We invited public comment on this proposal.

Comment: Many commenters expressed concern about reporting using the NHSN and noted that hospitals may be required to report COVID–19 vaccination data in multiple reporting systems. Some commenters requested CMS align with other HHS reporting systems, including HHS TeleTracking, and state reporting requirements to reduce burdensome duplicative reporting.

Response: We recognize that this measure may lead to duplicative reporting if hospitals voluntarily report COVID–19 HCP vaccination information to other data reporting systems in addition to the NHSN per Hospital IQR Program requirements. We are collaborating with other HHS agencies, including the CDC, to minimize reporting burden to the extent feasible.

Comment: Many commenters asserted that the frequency of reporting for the measure is overly burdensome. Some commenters recommended that hospitals report data once per quarter instead of one week per month.

Response: We appreciate commenters' concerns regarding reporting frequency; however, we respectfully disagree that the frequency is overly burdensome or that hospitals should report once per quarter instead of one week per month, because we believe that important public health initiatives currently outweigh the burden. We proposed that hospitals report at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline. We proposed that for each quarter, the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. We believe that, given the public health importance of vaccination in addressing the COVID–19 PHE, the benefits of requiring reporting outweigh the burden. We believe that reporting these data on a frequent interval would increase their value by allowing the CDC to better track these important public health data while also being a valuable quality measure that supports consumer choice and hospital improvement initiatives. Because the CDC requests data reported on a monthly basis for one week per month, we believe this is an appropriate reporting frequency for our quality measure to ensure that hospitals do not have duplicative reporting requirements to meet the CDC's need for public health data and CMS' quality measure reporting requirements.

Comment: A few commenters suggested that because the measure will provide information for a single point in time, it will quickly become outdated in the rapidly changing COVID–19 landscape, and thus would not be meaningful, nor would it reflect safety or quality of care. A commenter requested that CMS reconsider how the measure is calculated for public reporting. The commenter supported the concept of reporting one quarter of data. They recommend that after the first refresh, rather than calculating a summary measure of the COVID–19 vaccination coverage from the 3 monthly modules of data reported for the quarter during each refresh and adding one additional quarter of data to the measure calculation during each advancing refresh, until the point that four full quarters of data is reached, to use an alternate approach. They recommend updating the information monthly with only the most recent data, such that the measure would be consumed as the most recent quarter of data refreshed quarterly. They caution that averaging over 12 months would result in the dilution of the most recent, and potentially more meaningful information, and may actually discourage higher provider vaccine uptake rates since it would be harder to change performance on this measure.

Response: We refer readers to section IX.C.5.c. of this final rule for more details, where we are finalizing a modified version of our proposal. Based on public comment, we are not finalizing our proposal to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. Instead, we will only report the most recent quarter of data. This would result in more meaningful information that is up to date and not diluted with older data.

Comment: A few commenters suggested that CMS permit reporting of measure data in other systems or programs, including state-level reporting systems. These commenters supported data collection through the NHSN, but recommended it would be more appropriately captured through reporting programs other than the Hospital IQR Program.

Response: We thank the commenters for their recommendation. We believe that it is appropriate to report measure data through the NHSN for use in the Hospital IQR Program as hospitals have regular experience with NHSN to currently report HAIs and previously used the NHSN to report the Influenza Vaccination Coverage Among HCP (NQF #0431) measure, and that this measure is an appropriate addition to the program given the vulnerability of patients receiving care in inpatient hospitals and the importance of reducing transmission of COVID–19 among HCP and between HCP and patients. We note that this measure is also being finalized in a number of other quality programs based in different healthcare settings and aligned for reporting via NHSN, including the Inpatient Psychiatric Facility (IPF) Quality Reporting Program (FY 2022 IPF PPS final rule) as well as the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program and LTCH Quality Reporting Program discussed in section IX.D.5.a and IX.E.4.a, respectively, in this FY 2022 IPPS/LTCH PPS final rule.

As discussed in section IX.C.5.c. of this final rule, we are finalizing this measure with one modification to public reporting. We are not finalizing our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. Instead, we will only report the most recent quarter of data.

10. Validation of Hospital IQR Program Data

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25598 through 25600), we proposed changes to our Educational Review Process to extend the effects of the educational review

policy beginning with validations affecting the FY 2024 payment determination and for subsequent years. Previously we could only correct scores for the first 3 quarters of validation due to the inability to calculate the confidence interval in a timely manner for the 4th quarter of validation. We now believe it is feasible to calculate the confidence interval and use the corrected scores identified through an educational review for all 4 quarters of validation for chart-abstracted measures. This finalized update is described in detail in this section.

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41607 through 41608), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58942 through 58953) for detailed information on chart-abstracted and eCQM validation processes and previous updates to these processes for the Hospital IQR Program.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58952) where we summarized our validation policies in the following table:

	Quarters of Data Required for Validation	Scoring
Finalized Process for Validation Affecting the FY 2023 Payment Determination		
Chart-Abstracted Measures Validation: 400 Random Hospitals + up to 200 Targeted Hospitals	3Q 2020	At least 75% validation score
	4Q 2020	
eCQM Validation: Up to 200 Random Hospitals	1Q 2020 – 4Q 2020	Successful submission of at least 75% of requested medical records
Finalized Process for Validation Affecting the FY 2024 Payment Determination and Subsequent Years		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2021 – 4Q 2021	Chart-Abstracted Measures: At least 75% validation score (weighted at 100%) And eCQMs: Successful submission of at least 75% of requested medical records

b. Educational Review Process

(1) Chart-Abstracted Measures

(a) Background

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50260), we established an educational review process for validation of chart-abstracted measures. The process was subsequently updated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38402 through 38403). Under our educational review process, hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their validation results. Approximately 4 months after each quarter's validation submission deadline, validation results for chart-abstracted measures for the quarter are posted on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). Hospitals have 30 calendar days following the date validation results are posted to identify any potential CDAC or CMS errors for the first three quarters of validation results and contact the Validation Support Contractor (VSC) to request an educational review. Upon receipt of an educational review request, we review the data elements identified in the request, as well as the written justifications provided by the hospital. We provide the results of an educational review, outlining the findings of whether the scores were correct or incorrect, to the requesting hospital through a CMS-approved secure file transmission process (82 FR 38402).

If an educational review yields incorrect validation results for chart-abstracted measures, we use the corrected quarterly score, as recalculated during the educational review process to compute the final confidence interval (82 FR 38402). We use the revised score identified through an educational review when determining whether or not a hospital failed validation (82 FR 38402). Corrected scores, however, are only used if they indicate that the hospital performed more favorably than previously determined (82 FR 38402). We note that corrections only occur to calculations, not to the underlying measure data (82 FR 38402). Under the current policy, for the last quarter of validation for chart-abstracted measures, because of the need to calculate the confidence interval in a timely manner and the insufficient time available to conduct educational reviews, no educational reviews are available (82 FR 38403). The existing reconsideration process would be used to dispute an unsatisfactory validation result.

In the FY 2021 IPPS/LTCH PPS final rule, we finalized several policies to incrementally align the validation processes for chart-abstracted measure data and eCQM data in a stepwise process in the Hospital IQR Program (85 FR 58942 through 58952). As part of this policy, we updated the quarters of data required for validation for both chart-abstracted measures and eCQMs as summarized in these charts:

Previously Finalized Quarters Required for Validation Affecting FY 2023 Payment Determination (These quarters have been updated, as shown in the subsequent tables)		
Measures Submitted	**Required Quarters of Data for Validation**	**Validation Data Request Timeframe**
Chart-Abstracted Measures	3Q 2020	4Q 2020 – 1Q 2021
	4Q 2020	1Q – 2Q 2021
	1Q 2021	2Q-3Q 2021
	2Q 2021	3Q -4Q 2021
eCQMs	1Q 2020 - 4Q 2020	2Q – 3Q 2021

Current Quarters Required for Validation Affecting the FY 2023 Payment Determination	
Measures Submitted	**Required Quarters of Data for Validation**
Chart-Abstracted Measures	3Q 2020
	4Q 2020
eCQMs	1Q 2020 - 4Q 2020

Current Quarters Required for Validation Affecting the FY 2024 Payment Determination	
Measures Submitted	**Required Quarters of Data for Validation**
Chart-Abstracted Measures	1Q 2021
	2Q 2021
	3Q 2021
	4Q 2021
eCQMs	1Q 2021 - 4Q 2021

(b) Extending the Effects of the Educational Review Policy Beginning With Validations Affecting the FY 2024 Payment Determination and Subsequent Years

In light of the most recently finalized quarters included in validation, we proposed to extend the effects of the educational review policy beginning with validations affecting the FY 2024 payment determination and for subsequent years. As previously noted, in the past we could only correct scores for the first three quarters of validation due to the inability to calculate the confidence interval in a timely manner for the 4th quarter of validation. We now believe it is feasible to calculate the confidence interval and use the corrected scores identified through an educational review for all four quarters of validation for chart-abstracted measures, because the quarters used for validation are now early enough to calculate the confidence interval for the fourth quarter of validation in a timely manner. Specifically, under our previous policy, the quarters used for validation for the FY 2024 payment determination would have been 3Q 2021, 4Q 2021, 1Q 2022 and 2Q 2022. Under the most recently finalized policy, the quarters used for validation for the FY 2024 payment determination are 1Q 2021, 2Q 2021, 3Q 2021, and 4Q 2021. Therefore, we proposed to extend the effects of educational reviews for 4th quarter data such that if an error is identified during the education review process for 4th quarter data, we would use the corrected quarterly score to compute the final confidence interval used for payment determination.

All previously finalized policies with respect to education reviews would apply, such that approximately four months after each quarter's validation submission deadline, validation results for chart-abstracted measures for the quarter are posted on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). Hospitals have 30 calendar days following the date validation results are posted to identify any potential CDAC or CMS errors for the first three quarters of validation results and contact the Validation Support Contractor (VSC) to request an educational review. Upon receipt of an educational review request, we review the data elements identified in the request, as well as the written justifications provided by the hospital. We provide the results of an educational review, outlining the findings of whether the scores were correct or incorrect, to the requesting hospital through a CMS-approved secure file transmission process (82 FR 38402). If an educational review yields incorrect validation results for chart-abstracted measures, we use the corrected quarterly score, as recalculated during the educational review process to compute the final confidence interval (82 FR 38402). We use the revised score identified through an educational review when determining whether or not a hospital failed validation (82 FR 38402). Corrected scores, however, are only used if they indicate that the hospital performed more favorably than previously determined (82 FR 38402). We note that corrections only occur to calculations, not to the underlying measure data (82 FR 38402). We also note that under our proposal, as is currently the process, the quarterly validation reports for the chart-abstracted measures validation issued to hospitals would not be changed to reflect the updated score due to the burden associated with reissuing corrected reports (82 FR 38402).

In addition, our proposal did not apply to the educational review process for eCQMs, which is discussed in the next section.

We invited public comment on our proposal.

Comment: A commenter supported our proposal because it believes that the changes will help ensure accurate reporting.

Response: We thank the commenter for its support.

After consideration of the public comment we received, we are finalizing our proposal as proposed.

(2) Educational Review Process for eCQMs for Validation Affecting the FY 2023 Payment Determination and Subsequent Years

We refer readers to the FY 2021 IPPS/LTCH PPS (85 FR 58953) final rule where we finalized an educational review process for eCQM validation beginning with validations affecting the FY 2023 payment determination and for subsequent years (that is, starting with data from CY 2020). Under that process, hospitals receive eCQM validation results on an annual basis, and have the opportunity to request an educational review once annually following receipt of their results (85 FR 58953). We did not propose any changes to these policies in the proposed rule.

11. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements. We did not propose any changes to the policy in the proposed rule.

12. Public Display Requirements

a. Background

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the Care Compare website, or its successor website, after a 30-day preview period (78 FR 50776 through 50778). We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49712 through 49713), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41539), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58953) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Care Compare* website at *https://www.medicare.gov/care-compare,* or on other CMS websites such as: *medicare.gov/care-compare*. We did not propose any changes to these policies in the proposed rule. However, we refer readers to section IX.9.j., where we are finalizing a modified version of our proposed public reporting policy for the COVID–19 Vaccination Among HCP measure.

b. Public Reporting of eCQM Data

We direct readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58954 through 58959) where we finalized public reporting requirements of eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. We note that this policy incrementally increases the eCQM data publicly reported to four quarters of data for the CY 2023 reporting period/FY 2025 payment determination and subsequent years. We did not propose any changes to these policies in the proposed rule.

c. Overall Hospital Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Ratings). The Overall Star Ratings will utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital IQR Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule with comment period for details. We did not propose any changes to these policies in the proposed rule.

13. Reconsideration and Appeal Procedures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We did not propose any changes to these policies in the proposed rule.

14. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38409 through 38411), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE policy. We also refer readers to the QualityNet website at: *http://www.QualityNet.cms.gov* for our current requirements for submission of a request for an exception. We did not propose any changes to the policies in the proposed rule.

D. Updates to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program is authorized by section 1866(k) of the Act and applies to hospitals described in section 1886(d)(1)(B)(v) (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to all of the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53555 through 53567).
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50853).
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50286).
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723).
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193).
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425).
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41624).
- The CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59154).
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42509 through 42524).
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58959 through 58966).

2. Overview of Proposed Updates to the PCHQR Program and Requests for Information

In section IX.D.4. of the proposed rule, we proposed to remove the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) measure beginning with the FY 2024 program year (86 FR 25602). In section IX.D.5. of the preamble of the proposed rule, we proposed to adopt the COVID–19 Vaccination Coverage Among

Healthcare Personnel measure, beginning with the FY 2023 program year and for subsequent years (86 FR 25602 through 25605). In section I.X.D.9. of the preamble of the proposed rule, we proposed to update our terminology for this program by replacing the term ''QualityNet Administrator'' with ''QualityNet security official'' (86 FR 25607). In section IX.D.11. of the proposed rule, we proposed to codify existing PCHQR Program policies at 42 CFR 412.23(f)(3) and 42 CFR 412.24 (86 FR 25607 through 25608).

In section IX.D.2. of the preamble of the proposed rule, we also referred readers to section IX.B. of the preamble of the proposed rule (86 FR 25554 through 25561), Closing the Health Equity Gap in CMS Quality Programs—A Request for Information, where we requested information on our Equity Plan for Improving Quality in Medicare, which outlines our commitment to closing the health equity gap through improved data collection in order to better measure and analyze disparities across programs and policies. The request for information asked for public comment regarding the potential stratification of quality measure results by race and ethnicity and the potential creation of a hospital equity score in CMS quality reporting and value-based purchasing programs, including the PCHQR Program.

In section IX.D.2. of the preamble of the proposed rule, we also referred readers to section IX.A. of the preamble of the proposed rule (86 FR 25549 through 25554), where we requested information on potential actions we can take to expand the use of the FHIR standard (as described in that section) in furtherance of our goal to move fully to digital quality measurement in CMS quality reporting programs, including the PCHQR Program, and value-based purchasing programs by 2025.

3. Measure Retention and Removal Factors for the PCHQR Program

For a detailed discussion regarding our retention and removal factors, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183), where we adopted policies for measure retention and removal, and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611), where we updated our measure removal factors. We did not propose any changes to these policies in the proposed rule.

4. Removal of the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) Measure From the PCHQR Program Beginning With the FY 2024 Program Year

We proposed to remove the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) (''Oncology: Plan of Care for Pain'') measure from the PCHQR Program beginning with the FY 2024 program year based on Factor-7: *It is not feasible to implement the measure specifications* (86 FR 25602). We first adopted the Oncology: Plan of Care for Pain measure for the FY 2016 program year in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50842 through 50843) and we refer readers to this rule for a detailed discussion of the measure. We stated in the proposed rule that although we continue to believe the Oncology: Plan of Care for Pain measure provides important data for patients and hospitals in making decisions about care and informing quality improvement efforts, the measure steward has decided to revert to a previous version of the measure that requires a plan of care to address any, rather than just moderate-severe, pain and will no longer maintain the specifications for this measure as it is currently used in the PCHQR Program. In addition, the version of the measure that the measure steward has decided to revert to is designed to be paired with the *Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384)* measure (78 FR 50843), meaning they were developed to be used together (77 FR 53649). The *Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384)* measure was removed from the PCHQR Program's measure set beginning with the FY 2021 program year in the FY 2019 IPPS/LTCH PPS final rule because it was topped-out (83 FR 41611 through 41613).

We stated in the proposed rule that through our Meaningful Measures Framework, we continue to focus on proposing quality measures that will reduce reporting and regulatory burden on providers and accelerate the move to fully digital measures.[1233] In the FY 2014 IPPSLTCH PPS final rule, we stated our intention to simplify measure collection and submission, and to reduce the reporting burden of chart-abstracted measures (78 FR 50810). PCH–15 requires manual chart-abstraction, and we stated that we believed this proposal to remove it is aligned with the goals of the Meaningful Measures Initiative and a shift toward the use of digital quality measures. Further, the PCH–15 measure's mean and median for the past four years, including FY 2020, demonstrate very high performance with little variation among the 11 PCHs. Accordingly, because the version of the Oncology: Plan of Care for Pain measure that is currently used in the PCHQR Program will no longer be maintained by the measure steward, data show high performance on the measure with little variation, the updated version of the measure is designed to be used with the PCH–16 measure that we previously removed because it was topped-out, and the removal of chart-abstracted measures aligns with CMS goals to move to digital quality measures, we proposed to remove the Oncology: Plan of Care for Pain measure from the PCHQR measure set.

We invited public comment on our proposal to remove the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) measure from the PCHQR Program beginning with the FY 2024 program year.

Comment: A commenter supported the removal of the PCH–15 measure from the PCHQR measure set. The commenter further encouraged CMS to develop and include meaningful pain measures in the PCHQR Program in the future.

Response: We thank the commenter for its support of our proposal. We agree that actionable pain measures can provide important data for patients and hospitals in making decisions about care and informing quality improvement efforts and will consider their inclusion in the program in the future.

Comment: A few commenters opposed the removal of the Oncology: Plan of Care for Pain (PCH–15) Measure. Those commenters stated that the measure steward's decision to revert to an older version of the measure was appropriate because a care plan for any pain is necessary, not just moderate to severe pain, and that measuring pain is important to managing quality of life for cancer patients and the commenters believed that the measure should be updated and retained in the PCHQR Program. A commenter was concerned that the removal of the measure would undermine pain care and result in worse outcomes.

Response: We appreciate commenters' concerns and agree that appropriate pain management is important for patients receiving care in PCHs. As we noted in the proposed rule, the PCH–15

[1233] CMS List of Measures under Consideration for December 21, 2020. Accessed March 12, 2021. *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf.*

measure has shown consistently high performance across the 11 PCHs. We believe the consistency across all PCHs demonstrates their commitment to appropriate pain management for cancer patients and we believe this work will continue in the absence of this measure. We do not believe that removing the measure will result in worse patient outcomes.

Comment: A few commenters recommended that CMS retain the PCH–15 measure and reintroduce the Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384) Measure, noting that these measures were intended to be reported together. A commenter stated that the PCH–16 measure was removed from the PCHQR measure set because it was topped-out but asserted that this is only the case when the measure is manually reported instead of extracted from electronic health records or claims. A few commenters noted that both the PCH–15 and PCH–16 measures are currently reported in the Merit-based Incentive Payment System (MIPS), the Oncology Care Model (OCM), and the Radiation Oncology (RO) Model and suggested that retaining these measures in the PCHQR measure set would promote program alignment. Another commenter stated that both measures have been used since the Physician Quality Reporting System (PQRS) was introduced. A commenter noted that the NQF has endorsed both the PCH–15 and PCH–16 measures within the past year.

Response: We appreciate commenters' suggestions to reintroduce the PCH–16 measure. We also recognize that the measure, along with the PCH–15 measure, continues to be used in other quality reporting programs and was recently re-endorsed by the NQF. We considered retaining the PCH–15 measure and reintroducing the PCH–16 measure. However, as we noted in the FY 2019 IPPS/LTCH final rule, we removed the PCH–16 measure because it did not align with our policy goal to focus on outcome measures and did not support efforts to develop electronic clinical quality measure (eCQM) reporting for PCHs as part of our Meaningful Measures Framework [1234] (83 FR 41612). While we acknowledge that both measures are included in other quality reporting programs and that the measures are intended to be reported together, we note that the measure steward has reverted to a previous version of the measure and will no longer maintain the specifications for this measure as it is currently used in the PCHQR Program. We proposed to remove the PCH–15 measure because the benefits of retaining it have lessened and the measure steward has decided to revert to a previous version of the measure that requires a plan of care to address any, rather than just moderate-severe, pain and will no longer maintain the specifications for this measure as it is currently used in the PCHQR Program.

We acknowledge the comment that reporting the PCH–16 measure manually versus electronically or via claims would impact whether the measure is topped-out and will consider this information in the development of new measures for the PCHQR Program. We did not propose reintroducing the PCH–16 measure and retaining the PCH–15 measure in the proposed rule, and we believe the removal is justified given the high performance of PCHs on the measure in the PCHQR Program and the burden of reporting chart-abstracted measures.

After consideration of the public comments we received, we are finalizing the removal of the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) measure from the PCHQR Program beginning with the FY 2024 program year, without modification.

5. Adoption of the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning With the FY 2023 Program Year

a. Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[1235] COVID–19 is a contagious respiratory illness [1236] that can cause serious illness and death. Older individuals, racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[1237] [1238]

As stated in the proposed rule, as of April 2, the U.S. had reported over 30 million cases of COVID–19 and over 550,000 COVID–19 deaths. As of July 21, 2021, the U.S. has reported over 34 million cases of COVID 19 and over 607,000 COVID–19 deaths.[1239] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[1240] From December 2, 2020 to January 30, 2021, more than 100,000 Americans were in the hospital with COVID–19 at the same time.[1241]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[1242] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[1243] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[1244] [1245] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface.[1246] Subsequent to the publication of the

[1234] *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[1235] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[1236] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[1237] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[1238] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[1239] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker: COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[1240] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[1241] US Currently Hospitalized | The COVID Tracking Project. *Accessed January 31, 2021 at: https://covidtracking.com/data/charts/us-currently-hospitalized.*

[1242] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1243] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1244] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1245] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1246] *Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

proposed rule, the CDC has confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[1247] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed COVID–19 infection, regardless of whether the individual has symptoms.[1248] Although infections through inhalation at distances greater than six feet from an infectious source are less likely than at closer distances, the phenomenon has been repeatedly documented under certain preventable circumstances. These transmission events have involved the presence of an infectious person exhaling virus indoors for an extended time (more than 15 minutes and in some cases hours) leading to virus concentrations in the air space sufficient to transmit infections to people more than 6 feet away, and in some cases to people who have passed through that space soon after the infectious person left. Personal protective equipment (PPE) and other infection control precautions can reduce the likelihood of transmission in health care settings, but COVID–19 can still spread between health care personnel (HCP) and patients given the close contact that may occur during the provision of care.[1249] The CDC has emphasized that health care settings, including long-term care settings, can be high-risk places for COVID–19 exposure and transmission.[1250]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[1251] On December 11, 2020, the FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[1252] Subsequently, the FDA issued EUAs for additional COVID–19 vaccines.[1253] [1254]

As part of its national strategy to address COVID–19, the Biden Administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy and outlined a goal of administering 200 million shots in 100 days.[1255] After achieving this goal,[1256] the Biden Administration announced a new goal to administer at least one COVID–19 vaccine shot to 70 percent of the U.S. adult population by July 4, 2021.[1257] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including HCP providing direct care to patients with COVID–19, and individuals at highest risk for developing severe illness from COVID–19.[1258] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccine, given the potential for transmission in health care settings and the need to preserve health care system capacity.[1259] Research suggests most states followed this recommendation,[1260] and HCP began receiving the vaccine in mid-December of 2020.[1261]

Frontline healthcare workers, such as those employed in PCHs, are being prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the United States.[1262] As stated in the proposed rule, as of April 2, 2021, the CDC reported that over 162 million doses of COVID–19 vaccine had been administered, and approximately 60 million people had received full doses. As of July 2, 2021, over 328 million doses of COVID–19 vaccine had been administered, and approximately 155.9 million people had received a complete vaccination course.[1263] Subsequent to the publication of the proposed rule, on June 3, 2021 the White House confirmed that there was sufficient vaccine supply for all Americans.[1264] We stated in the

[1247] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[1248] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html*.

[1249] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission*.

[1250] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[1251] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[1252] U.S. Food and Drug Administration. (2021). Pfizer-BioNTech COVID–19 Vaccine. Available at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine*. U.S. Food and Drug Administration. (2021). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/150386/download*.

[1253] U.S. Food and Drug Administration. (2021). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download*.

[1254] U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download*.

[1255] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on April 3, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/*.

[1256] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 2, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/21/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations-2/*.

[1257] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 4, 2021, at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/05/04/fact-sheet-president-biden-to-announce-goal-to-administer-at-least-one-vaccine-shot-to-70-of-the-u-s-adult-population-by-july-4th/*.

[1258] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[1259] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[1260] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/*.

[1261] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f*.

[1262] Centers for Disease Control and Prevention. Healthcare Workers. (2017) Accessed February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html*.

[1263] Centers for Disease Control and Prevention. COVID Data Tracker. COVID–19 Vaccinations in the United States. (2021) Accessed on July 2, 2021. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations*.

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proposed rule that we believe it is important to require that PCHs report their rates of HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID–19 among their HCP, and to help sustain the ability of U.S. hospitals to continue serving their communities throughout the PHE and beyond. Therefore, we proposed a new measure, COVID–19 Vaccination Coverage Among HCP (COVID–19 vaccination measure), beginning with the FY 2023 program year. For that program year, PCHs would be required to report data on the measure for the fourth quarter of CY 2021 (that is, from October 2021 through December 2021). For more information about the proposed reporting period, we referred readers to section IX.D.5.c. of the preamble of the proposed rule. We also proposed that the measure would assess the proportion of a PCH's HCP that has been vaccinated against COVID–19.

Although data showing the effectiveness of COVID–19 vaccines to prevent asymptomatic infection or transmission of SARS-CoV–2 are limited at this time, we stated in the proposed rule that we believe PCHs should report their rates of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[1265] Data from influenza vaccination demonstrates that provider uptake of the vaccine is also associated with that provider recommending vaccination to patients,[1266] and we stated that we believe HCP COVID–19 vaccination in PCHs could similarly increase uptake among that patient population. We also stated that publishing the HCP vaccination rates will be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose PCHs from which to seek treatment. We further stated that under CMS' Meaningful Measures Framework, the COVID–19 HCP vaccination measure addresses the quality priority of ''Promote Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

b. Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure (''COVID–19 HCP vaccination measure'') is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-long-term care facilities such as PCHs.

(1) Measure Specifications

The denominator is the number of HCP eligible to work in the PCH for at least one day during the reporting period (as described in section IX.D.5.c.), excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[1267]

The numerator is the cumulative number of HCP eligible to work in the PCH for at least one day during the reporting period (as described in section IX.D.5.c. of the preamble of the proposed rule) and who received a complete vaccination course against COVID–19 using an FDA-authorized vaccine for COVID–19 (whether the FDA issued an approval or EUA). A complete vaccination course is defined under the specific FDA authorization (either the EUA or the approval) and may require multiple doses or regular revaccination.[1268] Vaccination coverage is defined, for purposes of this measure, as the percentage of HCP eligible to work at the PCH for at least one day who received a complete vaccination course against COVID–19. The proposed specifications for this measure are available at *https://www.cdc.gov/nhsn/nqf/index.html*.

(2) Review by the Measure Applications Partnership (MAP)

The COVID–19 HCP vaccination measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020,'' [1269] a list of measures under consideration for use in various Medicare programs. When the Measure Applications Partnership (MAP) Hospital Workgroup convened on January 11, 2021, it reviewed the measures on the MUC List, including the COVID–19 HCP vaccination measure. The MAP Hospital Workgroup recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the PCHQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[1270] The MAP Hospital Workgroup also stated that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to PCHs will allow PCHs to benchmark vaccine coverage rates and improve their vaccine coverage rates, and that reducing rates of COVID–19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[1271]

In its preliminary recommendations, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[1272] To mitigate its concerns, the MAP Hospital Workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[1273] Subsequently, the MAP Coordinating Committee met on January 25, 2021 and reviewed the COVID–19 Vaccination Coverage Among HCP measure. In the 2020–2021 MAP Final Recommendations issued March 11, 2021, the MAP offered conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications are further refined, specifically saying that ''the incomplete specifications require immediate mitigation and further development should continue.'' [1274] In its final report, the MAP noted that the measure would add value to the program measure set by providing visibility into an important intervention to limit COVID–19 infections in healthcare personnel and

White House. Accessed on July 21, 2021 at *https://www.whitehouse.gov/briefing-room/press-briefings/2021/06/03/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-40/*.

[1265] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*.

[1266] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[1267] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications*.

[1268] Measure Applications Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[1269] The National Quality Forum. (2021) Accessed March 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[1270] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[1271] *Ibid.*

[1272] *Ibid.*

[1273] *Ibid.*

[1274] Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on March 12, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020–2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC–LTC.aspx*.

the patients for whom they provide care.[1275]

In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with the MAP Coordinating Committee on March 15th. CMS and the CDC provided additional information to the MAP Coordinating Committee at that meeting that addressed vaccine availability, the alignment of the COVID–19 vaccination measure specifications as closely as possible with the Influenza HCP vaccination measure (NQF #0431) specifications, and the definition of HCP used in the measure. At this meeting, CMS and the CDC also presented preliminary findings from the testing of the numerator of COVID–19 Vaccination Coverage Among HCP, which is currently in process. These preliminary findings showed that the numerator data should be feasible and reliable. Testing of the numerator of the number of healthcare personnel vaccinated involves a comparison of vaccination data collected by the CDC directly from long-term care facilities (LTCs) through NHSN with vaccination data independently reported to the CDC through the Federal pharmacy partnership program. These are two completely independent data collection systems. In initial analyses of the first month of vaccination from December 2020 to January 2021 of HCP vaccination in approximately 1,200 facilities which reported to both systems, the number of healthcare personnel vaccinated was highly correlated between these 2 systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[1276] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we stated in the proposed rule that we believe these data indicate the measure is feasible and reliable for use in PCHs (86 FR 25605).

We stated in the proposed rule that we value the recommendations of the MAP and considered these recommendations carefully. Section 1890A(a)(4) of the Act requires the Secretary to take into consideration input from multi-stakeholder groups in selecting quality and efficiency measures. While we value input from the MAP, we also stated in the proposed rule that believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on PCHs and the vulnerable populations they serve. We continue to engage with the MAP to mitigate its concerns and appreciate the MAP's conditional support for the measure.

(3) NQF Endorsement

Section 1866(k)(3)(A) of the Act states that subject to subparagraph (B), any measure specified by the Secretary for the PCHQR Program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. Under section 1866(k)(3)(B), in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed COVID–19 Vaccination Coverage Among HCP measure is not NQF endorsed and has not been submitted to NQF for endorsement consideration. The CDC, in collaboration with CMS, is planning to submit the measure for consideration in the NQF Fall 2021 measure cycle.

Because this measure is not NQF-endorsed, we considered whether there are other available measures that assess COVID–19 vaccination rates among HCP. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP, therefore the exception in section 1866(k)(3)(B) of the Act applies.

c. Data Collection, Submission and Reporting

Given the time sensitive nature of this measure considering the current PHE, we proposed that for the FY 2023 program year, the reporting period for the proposed COVID–19 Vaccination Coverage Among HCP measure would be from October 1, 2021 through December 31, 2021. Thereafter, we proposed quarterly reporting deadlines for the PCHQR Program. PCHs would report the measure through the NHSN web-based surveillance system.[1277] PCHs currently use the NHSN web-based system to report five HAI measures for the PCHQR Program, as well as the Influenza Vaccination Coverage Among HCP (NQF #0431).

To report this measure, we proposed that PCHs would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet PCHQR Program requirements. While we stated in the proposed rule that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that PCHs would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a PCH's healthcare personnel while balancing the costs of reporting. If a PCH submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we proposed that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each PCH, which would be calculated by taking the average of the data from the three weekly rates submitted by the PCH for that quarter. CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

As described in section IX.D.5.b.(1). of the preamble of the proposed rule (86 FR 25605), PCHs would report the number of HCP eligible to have worked at the facility during the self-selected week that the PCH reports data for in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week.

[1275] Measure Applications Partnership. 2020–2021 Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on March 12, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020–2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC–LTC.aspx*.

[1276] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at: *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*; Gharpure R, Guo A, Bishnoi CK, et al. Early COVID–19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program—United States, December 2020–January 2021. MMWR Morb Mortal Wkly Rep 2021;70:178–182. DOI: *http://dx.doi.org/10.15585/mmwr.mm7005e2*.

[1277] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

We invited public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage Among HCP, to the PCHQR Program beginning with the FY 2023 program year, with an October 1, 2021 through December 31, 2021 reporting period for that program year, and continuing with quarterly reporting deadlines for subsequent PCHQR Program years.

Comment: Many commenters expressed their support for our proposal to adopt the COVID–19 Vaccination Coverage Among HCP Measure. A few commenters stated their belief that the measure supports PCHs, healthcare personnel, and the communities they serve. A few commenters recommended that CMS continue to work with stakeholders as the PHE evolves to ensure the measure remains appropriate and timely.

Response: We thank commenters for their support of the measure and agree that COVID–19 vaccination remains important. We intend to continue working with stakeholders as the commenters suggested.

Comment: A commenter expressed support for the measure specifications, noting that the entire radiation oncology team, not just physicians, have daily contact with patients over the course of their treatment and capturing vaccination status protects patients and staff.

Response: We thank the commenter for its support and agree that it is important to measure vaccination status throughout the PCH in order to protect patients and staff.

Comment: A few commenters were supportive of reporting the measure through the CDC NHSN. A commenter encouraged CMS to use the NHSN over other systems, including the HHS TeleTracking system, to promote consistency and reduce burden from duplicative reporting. Another commenter expressed support for NHSN and its ability to ensure transparency and accountability in reporting.

Response: We thank these commenters for their support.

Comment: A few commenters recommended that CMS consider incorporating reporting for other vaccines as part of the COVID–19 Vaccination Coverage Among HCP Measure. A commenter suggested that the measure include HCP coverage for pertussis vaccines. Another commenter encouraged CMS to retain the Influenza Vaccination Coverage Among HCP Measure (PCH–28/NQF #0431) in the PCHQR measure set.

Response: We thank commenters for their feedback and note that the Influenza Vaccination Coverage Among HCP Measure remains in the PCHQR Program. We will consider whether to incorporate reporting for additional vaccines in the future.

Comment: A few commenters recommended that CMS delay the proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure until more information on the long-term efficacy of the vaccines is clear. These commenters expressed concern regarding whether a booster vaccination will be required and whether the current measure may be premature given unknowns about the future of the PHE. Other commenters expressed concerns about potential unintended consequences of adding the measure into the program too quickly given the rapidly changing circumstances in which vaccines are being developed and deployed. Some commenters also asserted that tracking HCP vaccination will be complicated until information on boosters becomes available.

Response: We appreciate commenters' concerns about the duration of vaccine efficacy and the potential need for boosters. The COVID–19 Vaccination Coverage Among HCP measure is a measure of a completed vaccination course (as defined in the measure specifications [1278]) and does not address booster shots. Currently, the need for COVID–19 booster doses has not been established, and no additional doses are currently recommended for HCP.[1279] However, we believe that the numerator is sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' and therefore the measure is sufficiently specified to address boosters. While we recognize commenters' concerns that the measure has been proposed quickly, the COVID–19 PHE has significantly impacted PCHs and their patients and we do not agree that adoption is premature. The intent of adopting the COVID–19 Vaccination Coverage Among HCP measure is to collect and report data that will support public health tracking and provide beneficiaries and their caregivers information to support informed decision making. For these reasons, we believe that it is appropriate to collect and report this data as soon as possible.

Comment: A few commenters noted that, presently, all COVID–19 vaccines are authorized through an EUA and that some individuals remain hesitant to receive vaccination while the vaccine is authorized by an EUA. These commenters stated that the measure is premature until such time that a vaccine has received full FDA approval. A few commenters recommended that, if a delay is not possible, reporting for the measure should be voluntary for at least the first year.

Response: While we support widespread vaccination coverage, we also understand that some HCP may be concerned about receiving the COVID–19 vaccine prior to the vaccine receiving full FDA approval. Although we recognize there are differences between EUA authorization and full FDA approval, we note that the process for each is scientifically rigorous. Each vaccine manufacturer that received EUA authorization enrolled tens of thousands of participants in randomized clinical trials, which is similar to what is required for full FDA approval.[1280] Manufacturers submit the same robust and rigorous data for both an EUA authorization and full FDA approval, and more than 330 million doses of COVID–19 vaccines authorized by EUAs have been administered.[1281] We believe these vaccines have been proven to be safe and effective. The COVID–19 Vaccination Coverage Among HCP measure is also a process measure that assesses HCP vaccination coverage rates, not an outcome measure for which PCHs are held directly accountable for a particular outcome. As stated previously, the intent of adopting the COVID–19 Vaccination Coverage Among HCP measure is to collect and report data that will support public health tracking and provide beneficiaries and their caregivers information to support informed decision making. For these reasons, we believe that it is appropriate to collect and report this data as soon as possible.

Comment: A few commenters expressed concerns about the measure's numerator and denominator. A commenter noted that the measure numerator differs from the Influenza Vaccination Coverage Among HCP (NQF #0431) measure. The commenter noted several differences in data elements reported in NHSN, including the

[1278] CDC. Measure Specification: NHSN COVID–19 Vaccination Coverage. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[1279] Centers for Disease Control and Prevention. Vaccine Administration. Available at *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.* Accessed June 25, 2021.

[1280] Harvard Law Petrie-Flom Center. ''What's the Difference Between Vaccine Approval (BLA) and Authorization (EUA)?'' June 15, 2021. Available at: *https://blog.petrieflom.law.harvard.edu/2021/06/15/whats-the-difference-between-vaccine-approval-bla-and-authorization-eua/.*

[1281] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker: COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations (Accessed on July 19, 2021).*

possibility for one or two doses, the potential for future boosters, variance in vaccine supply, and the option to select ''offered but declined vaccine'' or ''adverse event following vaccination.''

A commenter asserted that the denominator, which defines HCP to include all HCP who receive a direct paycheck from the hospital regardless of clinical responsibility or patient contact, is too broad of a population and is problematic. The commenter further stated that significant resources would be required to document the vaccination status of all employees, many of whom received vaccines from third parties. A commenter argued that it will be challenging to collect the full and accurate count of adult students, trainees, and volunteers as these individuals are not always captured or identified as such in human resources or hospital databases.

A few commenters expressed concerns about the potential impact of state legislation or regulation that may limit ability to require vaccination or request vaccine status from HCP.

Response: We appreciate commenters' concerns regarding the differences in the numerator specifications for the Influenza Vaccination Coverage Among HCP measure (NQF #0431). While we have sought to align this measure with the Influenza Vaccination Coverage Among HCP measure (NQF #0431), each measure addresses different public health initiatives and different vaccines, and therefore the measure specifications cannot be in complete alignment. For example, influenza is seasonal and influenza vaccines are therefore only delivered during influenza season (October 1 through March 31). We believe that, given the public health importance of vaccination in addressing the COVID–19 PHE, the benefits of requiring additional reporting outweigh the burden. We also note that although this information is not captured in the numerator or denominator, the CDC's NHSN tool allows hospitals to indicate that HCP were offered a vaccination but declined.[1282]

We recognize that some PCHs may still be obtaining vaccination records from their employees and other personnel that work within their hospitals. With respect to the concern that some PCHs may have incomplete data to report, we acknowledge the logistical challenges of collecting vaccination status for all HCPs within a PCH. However, given the highly contagious nature of COVID–19, we believe the information is important for patients, including particularly vulnerable individuals such as cancer patients.

With regard to concerns about state-level legislation that may limit a PCH's ability to require vaccination or request vaccine status from HCP, we reiterate that the COVID–19 Vaccination Coverage Among HCP measure does not require HCP to receive the vaccination and is a process measure that assesses HCP vaccination coverage rates, not an outcome measure for which PCHs are held directly accountable for a particular outcome. While we are aware that at least one state has enacted legislation that prohibits employers from requiring employees to disclose immunization status,[1283] we are not aware of any state legislation that prohibits employers from requesting voluntary reporting of immunization status. Additionally, the Equal Employment Opportunity Commission (EEOC) released updated and expanded technical assistance on May 28, 2021,[1284] stating that Federal equal employment opportunity (EEO) laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations. We again note that this measure does not require HCP to receive a COVID–19 vaccine and it does not require HCP to report their vaccination status. Therefore, we do not believe that this measure conflicts with any Federal or state-level requirements and believe that it is appropriate to require PCHs to report these data.

Comment: Several commenters expressed concerns about the exclusion of HCP with contraindications to COVID–19 vaccination in the denominator of the measure specifications. These commenters noted that data on HCP medical contraindications are not captured in hospital human resources databases or employee electronic health records, and therefore, hospitals are unable to exclude those individuals from the denominator of the measure, which may lead to inaccurate reporting and data collection burden. A commenter stated that this problem is compounded by the fact that indications and contraindications for the COVID–19 vaccines have changed and may continue to evolve as the disease is better understood. A commenter recommended CMS update the denominator to include all HCP with a clear explanation in public reporting that the denominator did not exclude HCP with contraindications, asserting that this change would allow for consistent cross-provider reporting and more accurate measurement and comparisons.

A commenter stated that the exclusion of HCP with contraindications alone is too narrow, noting that the Equal Employment Opportunity Commission (EEOC) requires employers to provide reasonable accommodations for employees with religious beliefs, practices or observances that prevent them from receiving vaccination and stating that HCP with such religious beliefs should be excluded as well.

Response: Regarding the difficulty in capturing contraindication information in order to exclude such HCP from the denominator of the measure specifications, we note that PCHs must report HCP who have contraindications as part of the influenza vaccine measure,[1285] and therefore we believe collecting contraindication information from HCP is feasible.

Regarding the comment that only excluded HCP with contraindications is too narrow and that HCP who refuse the vaccine for other reasons should also be excluded, we recognize that there are many reasons, including religious objections, that may lead individual HCP to decline vaccination. We note that the intent of the measure is to capture the vaccination rate within PCHs so that patients have information available on HCP vaccination to inform their health care decisions. Additionally, because the measure does not require vaccination, we do not believe this proposal conflicts with the reasonable accommodation requirements of the EEOC.

Comment: Some commenters expressed concern that the measure lacks NQF endorsement and stated that the measure requires refinement. A few commenters noted that lack of NQF

[1282] *https://www.cdc.gov/nhsn/forms/instr/57.220-toi-508.pdf.*

[1283] Montana House Bill 0702 (enacted May 7, 2021). Bill text available at: *https://leg.mt.gov/bills/2021/billpdf/HB0702.pdf.* Bill status including enactment available at: *http://laws.leg.mt.gov/legprd/LAW0203W$BSRV.ActionQuery?P_SESS=20211&P_BLTP_BILL_TYP_CD=HB&P_BILL_NO=0702&P_BILL_DFT_NO=&P_CHPT_NO=&Z_ACTION=Find&P_ENTY_ID_SEQ2=&P_SBJT_SBJ_CD=&P_ENTY_ID_SEQ=.*

[1284] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.* Accessed June 25, 2021.

[1285] CDC. Monitor Influenza Vaccination Coverage among your Health Care Personnel. Available at *https://www.cdc.gov/flu/toolkit/long-term-care/reporting.htm.*

endorsement is especially concerning for vaccines approved under EUAs. A commenter stated that, while it supports the measure, it has concerns about the use of the vaccination in certain populations (that is, pregnant women, immunocompromised individuals) without further study and encouraged CMS to pursue NQF endorsement in the future.

Response: We believe that in the context of the current COVID–19 PHE and continued monitoring and surveillance following the PHE, it is important to adopt this measure as quickly as possible to allow tracking and reporting of COVID–19 Vaccination Coverage Among HCP. This tracking would allow PCHs to identify the appropriateness and effectiveness of their initiatives to improve vaccination coverage and would provide patients and consumers with important information. We, therefore, believe it is appropriate to use the exception provided in section 1886(k)(3)(A) of the Act to adopt this measure because we assessed there is no NQF endorsed measure on the topic of COVID–19 vaccination coverage among healthcare personnel. The CDC, in collaboration with CMS, is planning to submit the measure for consideration in the NQF Fall 2021 measure cycle.

Comment: Several commenters opposed our proposal to adopt the COVID–19 Vaccination Coverage Among HCP Measure. A commenter noted that PCHs may be required to report COVID–19 vaccination information in multiple systems and recommended a single point of reporting. A commenter stated that it supports COVID–19 vaccination efforts but believes that CMS should not adopt the measure and instead focus on supporting vaccination efforts in provider settings.

Response: We agree that it is important to support vaccination efforts in provider settings. We believe that it is appropriate to use quality reporting program measures to encourage such efforts by collecting data on vaccination coverage among HCP. We do recognize that this measure may lead to duplicative reporting requirements if PCHs voluntarily report COVID–19 HCP vaccination information to data reporting systems other than NHSN, and we are collaborating with other HHS agencies, including the CDC, to ensure minimal reporting burden and to eliminate duplicative requirements to the extent feasible.

Comment: Several commenters opposed mandatory data submission via NHSN for the measure beginning October 1, 2021. A commenter noted that vaccination is progressing differently in each state and hospitals may not have tracking programs in place at that time. A commenter expressed concern about the impact that multiple state and Federal reporting requirements may have on hospitals. A few commenters recommended CMS delay implementation of the measure for at least one full calendar year until the FY 2024 program year when hospitals are fully capable of reporting and data will be more representative of fully vaccinated HCP. Some commenters suggested voluntary reporting for the first year.

Response: We believe that in the context of the current COVID–19 PHE and continued monitoring and surveillance following the PHE, it is important to adopt this measure as quickly as possible to allow tracking and reporting of COVID–19 Vaccination Coverage Among HCP. While we recognize that the data may not fully represent all activities to prevent and control infections, we do believe that the ongoing nature of the PHE demonstrates the importance of reporting HCP vaccination rates in PCHs as quickly as possible.

Comment: Several commenters opposed publicly reporting PCH performance on the proposed COVID–19 vaccination measure. A commenter asserted that the country is still in the early phases of deploying vaccines and changes to supply, strategy, or disease course could lead to unreliable data for the public. Another commenter expressed concern that publicly reporting measure data that may be skewed due to insufficient response time, refusal to receive the vaccine, or refusal from HCP to provide vaccination status, and that such skewed data may further fuel vaccine hesitancy. A few commenters believed measure data should not be publicly reported until vaccines receive full FDA approval.

Response: We believe that HCP vaccination is important to prevent the spread of COVID–19 and encourage HCP to disclose their vaccination status. While we recognize that HCP may decline to provide their vaccination status to PCHs, we disagree that such declinations would result in unreliable data. We also respectfully disagree that public reporting of vaccination data will discourage HCP vaccine uptake. We note that the national average of HCP who had received the influenza vaccination, as reported on the then Hospital Compare website, was 85 percent, 80 percent, and 82 percent respectively for FY 2017, 2018, and 2019 PCHQR Program years. The average of HCP within PCHs who had received the influenza vaccine in FY 2020 was even higher at 89 percent.[1286] We do not believe that this represents performance that suggests a negative relationship between public reporting and vaccine uptake among HCP and we believe that publicly reporting the data will be useful to consumers in choosing healthcare providers, including by making comparisons between PCHs.

However, with regard to concerns that data may be skewed by insufficient response time or hesitancies among HCP to receive the vaccine or report that they have received the vaccine, we believe it is important to make the most up-to-date and accurate data available to beneficiaries, which will support them in making essential decisions about health care. Based on these concerns, we will update the public reporting to use quarterly reporting, as opposed to averaging over four rolling quarters, which allows the most recent quarter data to be displayed without combining it with older quarters of data. This would result in information that is more up to date than it would be if it was diluted with older data. This update does not affect the data collection schedule established for submitting data to NHSN for the COVID–19 vaccination measure. This would simply update the data that are displayed for the public reporting purposes.

After consideration of the public comments we received, we are finalizing the proposal to adopt the COVID–19 Vaccination Coverage Among HCP, to the PCHQR Program beginning with the FY 2023 program year, with an October 1, 2021 through December 31, 2021 reporting period for that program year, and continuing with quarterly reporting deadlines for subsequent PCHQR program years. However, based on public comment, we will not finalize our plan to publicly report data averaged over four rolling quarters. We will instead only report the most recent quarter of data. This would result in more meaningful information that is up to date and not diluted with older data.

6. Summary of PCHQR Program Measures for the FY 2023 Program Year and Subsequent Years

This table summarizes the PCHQR Program measure set for the FY 2023 program year and subsequent years including the adoption of the COVID–19

[1286] CMS Provider Data Catalog. Cancer Treatment Measures—PPS-Exempt Cancer Hospital. Available at: *https://data.cms.gov/provider-data/dataset/k653-4ka8.*

Vaccination Coverage Among HCP measure as finalized in this final rule.

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FY 2023 PCHQR Program Measure Set and Subsequent Years

Short Name	NQF Number	Measure Name
Safety and Healthcare-Associated Infection (HAI) Measures		
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	0139	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure
HCP	0431	Influenza Vaccination Coverage Among Healthcare Personnel
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery]
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
COVID-19 HCP Vaccination	N/A	COVID-19 Vaccination Coverage Among HCP*
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice
N/A	0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology**
Intermediate Clinical Outcome Measures		
EOL-ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life
EOL-3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days
Patient Engagement/Experience of Care Measure		
HCAHPS	0166	HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients
N/A	N/A	Surgical Treatment Complications for Localized Prostate Cancer

* As discussed in section IX.D.5. of this final rule, we are finalizing this measure for adoption beginning with FY 2023.

** As discussed in section IX.D.4. of this final rule, we are finalizing this measure for removal beginning with FY 2024.

7. Maintenance of Technical Specifications for Quality Measures

We maintain and periodically update technical specifications for the PCHQR Program measures. The specifications may be found on the QualityNet website at: *https://qualitynet.cms.gov/pch*. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), where we adopted a policy to use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We did not propose any changes to our processes for maintaining technical specifications for PCHQR Program measures.

8. Public Display Requirements

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. For additional information regarding previously finalized public display requirements and policies, we refer readers to previous final rules.

In the table that follows, we summarize our current public display requirements for the PCHQR Program measures. The PCHQR measures' performance data is made publicly available on a CMS website, which is currently the Provider Data Catalog, available at: *https://data.cms.gov/provider-data/*. We did not propose any changes to these public display requirements.

Finalized Public Display Requirements for PCHQR Program

Summary of Finalized Public Display Requirements	
Measures	**Public Reporting**
• HCAHPS (NQF #0166) • Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383)*	2016 and subsequent years
• American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) • National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	2019 and subsequent years
• Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	April 2020 and subsequent years
• CAUTI (NQF #0138) • CLABSI (NQF #0139)	Deferred until CY 2022

**As discussed in section IX.D.4. of this final rule, we are finalizing this measure for removal, beginning with the FY 2024 program year.*

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9. Form, Manner, and Timing of Data Submissions

a. Procedural Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53567) for our previously finalized procedural requirements for the PCHQR Program. Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website.

b. Update of the Reference to QualityNet Administrator

In section IX.D.9. of the proposed rule, we stated that under our current procedural requirements, each PCH that participates in the PCHQR Program must identify one or more QualityNet Administrators who will follow the registration process located on the QualityNet website (*https://qualitynet.cms.gov*) (77 FR 53563).

In the proposed rule, we proposed to use the term ''QualityNet security official'' instead of ''QualityNet Administrator'' to align with the terminology we use or proposed to use in other quality reporting programs. We stated that this proposed update in terminology would not change the individual's responsibilities or add burden.

Additionally, we clarified that failing to maintain an active QualityNet security official once a PCH has successfully registered to participate in the PCHQR Program will not result in a finding that the PCH did not successfully participate in the PCHQR Program.

We invited public comment on our proposal to replace the term ''QualityNet administrator'' with ''QualityNet security official.''

Comment: A commenter supported CMS' proposal to replace the term ''QualityNet administrator'' with ''QualityNet security official'' and appreciated the clarification regarding maintaining an active QualityNet security official.

Response: We thank the commenter for its support.

After consideration of the public comments we received, we are finalizing the proposal to replace the term ''QualityNet administrator'' with ''QualityNet security official'' and are codifying this update at 42 CFR 412.24(b)(1), without modification.

10. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624), for a discussion of the Extraordinary Circumstances Exceptions (ECE) policy under the PCHQR Program. We did not propose any changes to this policy.

11. Codification of PCHQR Program Requirements at New 42 CFR 412.23(f) and New 42 CFR 412.24 of Our Regulations

There are currently no codified PCHQR Program requirements in our regulations. Accordingly, as we have done with a number of other CMS quality reporting programs, we proposed to add a new section at 42 CFR 412.24 entitled, ''Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program'' that codifies the program requirements listed in this proposed rule and a new paragraph (3) to 42 CFR 412.23(f) that requires cancer hospitals that participate in the PCHQR Program to follow all such program requirements (86 FR 25607 through 25608). We stated that we believe that the codification of these requirements will make it easier for stakeholders to find these requirements.

Specifically, we proposed to amend 42 CFR 412.23(f) by adding a new paragraph (3) that requires cancer hospitals, as classified under that paragraph, participating in the PCHQR Program to follow all requirements listed in the new section 42 CFR 412.24. We also proposed to add a new section at 42 CFR 412.24 that contains the regulations that govern the PCHQR Program—

- Program participation requirements (adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563)) including the PCHQR Program registration process;
- Data submission requirements for quality measures (adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563)) that are selected by CMS under section 1866(k) of the Act and must be submitted in a form and manner, and at a time, specified by CMS;
- Quality measure removal and retention factors (adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR

57182 through 57183) and expanded in FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611));

- Public reporting requirements for quality measure data reported by PCHs, with measure information displayed on the CMS website (adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191)); and
- Our extraordinary circumstances exception policy (adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848) and updated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38424 through 38425)) detailing the process for CMS to grant an extension or exception to quality measure reporting requirements under the PCHQR Program.

We welcomed public comment on the proposed codification of these existing PCHQR Program policies.

Comment: A few commenters supported the proposal to codify exiting PCHQR program requirements, but a commenter suggested that CMS codify them in the regulations under 42 CFR part 489, which the commenter believed implements section 1866(k) of the Act, the statutory basis of the program.

Response: We thank the commenters for their feedback. We believe that Part 412 is the appropriate placement for the PCHQR Program requirements because that Part includes regulations that govern the quality reporting programs for other providers excluded from IPPS, including long-term care hospitals, inpatient rehabilitation hospitals, and inpatient psychiatric hospitals.

After consideration of the public comments we received, we are finalizing the proposal to codify existing PCHQR Program policies at § 412.24. We are also codifying at § 412.1(a)(7) that the 42 CFR part 412 includes the implementation of section 1866(k), which directs hospitals described in section 1886(d)(1)(B)(v) of the Act to submit data on quality measures to the Secretary, and at revised § 412.1(b)(2) that Subpart B includes requirements for the PCHQR Program.

E. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as Long-Term Care Hospitals (LTCHs). Section 1886(m)(5)(C) of the Act requires LTCHs to submit to the Secretary quality measure data specified under section 1886(m)(5)(D) in a form and manner, and at a time, specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, resource use or other measures under section 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. LTCHs must submit the data required under section 1886(m)(5)(F) of the Act in the form and manner, and at the time, specified by the Secretary. Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. For more information on the background for the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51744), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50853), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49725), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57193), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38425 through 38426), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42524 through 42591). For more information on the requirements under the LTCH QRP, we refer readers to 42 CFR 412.560.

2. General Considerations Used for the Selection of Quality Measures for the LTCH QRP

For a detailed discussion of the considerations we historically use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728).

3. Quality Measures Currently Adopted for the FY 2022 LTCH QRP

The LTCH QRP currently has 17 measures for the FY 2022 LTCH QRP, which are set out in the following Table FF1. For a discussion of the factors used to evaluate whether a measure should be removed from the LTCH QRP, we refer readers to FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634) and to the regulations at 42 CFR 412.560(b)(3).

TABLE FF1. QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2022 LTCH QRP

Short Name	Measure Name & Data Source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Application of Functional Assessment/ Care Plan	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632)
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
Ventilator Liberation	Ventilator Liberation Rate
TOH–Provider*	Transfer of Health Information to the Provider Post-Acute Care (PAC)
TOH–Patient*	Transfer of Health Information to the Patient Post-Acute Care (PAC)
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) (NQF #3562)
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) (NQF #3480)
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

*In response to the COVID-19 public health emergency (PHE), we released an interim final rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the Transfer of Health Information measures for at least one full fiscal year after the end of the PHE.

4. LTCH QRP Quality Measure Beginning with the FY 2023 LTCH QRP

Section 1899B(h)(1) of the Act permits the Secretary to remove, suspend, or add quality measures or resource use or other measures described in sections 1899B(c)(1) or (d)(1) of the Act respectively, so long as the Secretary publishes in the **Federal Register** (with a notice and comment period) a justification for such removal, suspension, or addition. We proposed to adopt one new measure, the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) [1287] measure as an ''other'' measure under section 1899B(d)(1) of the Act beginning with the FY 2023 LTCH QRP. In accordance with section 1899B(a)(1)(B) of the Act, the data used to calculate this measure are standardized and interoperable. The proposed measure supports the Meaningful Measures domain of Promote Effective Prevention and Treatment of Chronic Disease. CMS identified the measure concept as a priority in response to the current public health crisis. This process measure was developed with the Centers for Disease Control and Prevention (CDC) to track COVID–19 vaccination coverage among HCP in the LTCH setting. This measure is described in more detail later in this section.

In addition, we proposed to update the denominator for one measure, the Transfer of Health (TOH) Information to the Patient–Post-Acute Care (PAC) measure to exclude patients discharged home under the care of an organized home health service or hospice. a. COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) Measure Beginning with the FY 2023 LTCH QRP.

(1) Background

On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS-CoV–2, a novel (new)

[1287] The measure steward changed the name of the measure from SARS-CoV–2 Vaccination Coverage among Healthcare Personnel to COVID–19 Vaccination Coverage among Healthcare Personnel. There were no changes to the measure itself, other than the name change.

coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[1288] COVID–19 is a contagious respiratory infection[1289] that can cause serious illness and death. Older individuals, racial and ethnic minorities,[1290] and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[1291] As of April 10, 2021, the U.S. reported over 30 million cases of COVID–19 and over 558,000 COVID–19 deaths.[1292] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased. [1293] In December 2020 and January 2021, media outlets reported that more than 100,000 Americans were in the hospital with COVID–19.[1294]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[1295] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[1296] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface [1297] and is not thought to be a common way that COVID–19 spreads, and that in certain circumstances, infection can occur through airborne transmission.[1298]

According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[1299] Subsequent to the publication of the proposed rule, the CDC has confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[1300] Personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in healthcare settings, COVID–19 can spread between healthcare personnel (HCP) and patients given the close contact that may occur during the provision of care.[1301] The CDC has emphasized that healthcare settings, including LTCHs, can be high-risk places for COVID–19 exposure and transmission.[1302] Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[1303]

On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[1304] Subsequently the FDA issued EUAs for additional COVID–19 vaccines. In issuing these EUAs, the FDA determined that it was reasonable to conclude that the known and potential benefits of each vaccine, when used as authorized to prevent COVID–19, outweighed its known and potential risks.[1305] [1306] [1307]

As part of its national strategy to address COVID–19, the Biden-Harris administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[1308] After achieve this goal,[1309] the Biden-Harris Administration announced a new goal to administer at least one COVID–19 vaccine shot to 70 percent of the U.S. adult population by July 4, 2021.[1310] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including healthcare personnel (HCP), and

[1288] U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[1289] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[1290] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html*.

[1291] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[1292] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[1293] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895*. Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html*.

[1294] NPR. U.S. Hits 100,000 COVID–19 Hospitalizations, Breaks Daily Death Record. Dec. 2, 2020. Accessed on December 17, 2020 at *https://www.npr.org/sections/coronavirus-live-updates/2020/12/02/941902471/u-s-hits-100-000-covid-19-hospitalizations-breaks-daily-death-record*; The Wall Street Journal. Coronavirus Live Updates: U.S. Hospitalizations, Newly Reported Cases, Deaths Edge Downward. Accessed on January 11 at *https://www.wsj.com/livecoverage/covid-2021-01-11*.

[1295] Centers for Disease Control and Prevention. (2021). COVID–19. Your Health. Frequently Asked Questions. *Accessed on January 11, 2021 at: https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[1296] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. *Accessed on January 11, 2021 at: https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[1297] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. *Accessed on January 11, 2021 at: https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[1298] Centers for Disease Control and Prevention. (2020). Centers for Disease Control Scientific Brief: SARS-CoV–2 and Potential Airborne Transmission. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-sars-cov-2.html*.

[1299] Centers for Disease Control and Prevention. (2020). Clinical Questions about COVID–19: Questions and Answers. Accessed on December 2, 2020 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html*.

[1300] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[1301] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on December 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html*.

[1302] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[1303] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[1304] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download*.

[1305] Ibid.

[1306] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download*.

[1307] U.S. Food and Drug Administration (2020). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download*.

[1308] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. March 29, 2021. Accessed at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/*.

[1309] U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download*.

[1310] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 4, 2021, at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/05/04/fact-sheet-president-biden-to-announce-goal-to-administer-at-least-one-vaccine-shot-to-70-of-the-u-s-adult-population-by-july-4th/*.

individuals at highest risk for developing severe illness from COVID–19.[1311] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in healthcare settings and the need to preserve healthcare system capacity.[1312] Research suggests most states followed this recommendation,[1313] and HCP began receiving the vaccine in mid-December of 2020.[1314] Subsequent to the publication of the SNF PPS proposed rule, on April 8, 2021, the White House confirmed that there was sufficient vaccine supply for all Americans.[1315]

HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. We believe it is important to require that LTCHs report COVID–19 HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID–19 among their HCP, reduce the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of LTCHs to continue serving their communities throughout the PHE and beyond.

We also believe that publishing facility-level COVID–19 HCP vaccination rates on Care Compare would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under the Meaningful Measures framework, the COVID–19 Vaccination Coverage among Healthcare Personnel measure addresses the quality priority of ''Promote Effective Prevention & Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

Therefore, we proposed a new measure, COVID–19 Vaccination Coverage among HCP to assess the proportion of an LTCH's healthcare workforce that has been vaccinated against COVID–19.

(2) Stakeholder Input

In our development and specification of the measure, a transparent process was employed to seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, under section 1890A of the Act.[1316] To meet this requirement, the following opportunity was provided for stakeholder input.

The pre-rule making process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List that the Secretary is considering adopting, through Federal rulemaking process, for use in Medicare program(s). This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list. The COVID–19 Vaccination Coverage among Healthcare Personnel measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List).[1317] Five comments were received from industry stakeholders during the pre-rulemaking process on the COVID–19 Vaccination Coverage among HCP measure, and support was mixed. Commenters generally supported the concept of the measure. However, there was concern about the availability of the vaccine and measure definition for HCP, and some commenters encouraged CMS to continue to update the measure as new evidence comes in.

(3) Measure Applications Partnership (MAP) Review

When the Measure Applications Partnership (MAP) Post-Acute Care/Long-Term Care (PAC–LTC) Workgroup convened on January 11, 2021, it reviewed the MUC List and the COVID–19 Vaccination Coverage among HCP measure. The MAP recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the LTCH QRP measure set by providing transparency about an important COVID–19 intervention to help limit COVID–19 infections.[1318] The MAP also stated that collecting information on COVID–19 vaccination coverage among healthcare personnel and providing feedback to facilities would allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing rates of COVID–19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[1319]

In its preliminary recommendations, the MAP PAC–LTC Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[1320] To mitigate its concerns, the MAP believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[1321] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 Vaccination Coverage among Healthcare Personnel measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measures back to MAP once the specifications are further clarified. The final MAP report is available at *http://www.qualityforum.org/Publications/2021/03/MAP_2020–2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC–LTC.aspx*.

In response to the MAP request for CMS to bring the measure back once the specifications were further clarified, CMS met with the MAP Coordinating Committee on March 15, 2021. First, CMS and CDC clarified the alignment of

[1311] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[1312] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[1313] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/*.

[1314] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f*.

[1315] Press Briefing by White House COVID–19 Response Team and Public Health Officials | The White House.

[1316] Centers for Medicare & Medicaid Services. Pre-rulemaking. Accessed at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking*.

[1317] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 12, 2021.

[1318] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on February 3, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650*.

[1319] Ibid.

[1320] Ibid.

[1321] Ibid.

the COVID–19 Vaccination Coverage among HCP with the Influenza Vaccination Coverage among HCP (NQF #0431), an NQF-endorsed measure since 2012. The COVID–19 Vaccination Coverage among HCP measure is calculated using the same approach as the Influenza Vaccination Coverage among HCP measure.[1322] The approach to identifying HCPs eligible for the COVID–19 vaccination is analogous to those used in the NQF endorsed flu measure which underwent rigorous review from technical experts about the validity of that approach and for which ultimately received NQF endorsement. More recently, prospective cohorts of health care personnel, first responders, and other essential and frontline workers over 13 weeks in eight U.S. locations confirmed that authorized COVID–19 vaccines are highly effective in real-world conditions. Vaccine effectiveness of full immunization with two doses of vaccines was 90 percent.[1323]

Additionally, to support the measure's data element validity, the CDC conducted testing of the COVID–19 vaccination numerator using data collected through the NHSN and independently reported through the Federal Pharmacy Partnership for Long-term Care Program for delivering vaccines to long-term care facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination for approximately 1,200 facilities that had data from both systems, the number of HCP vaccinated was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting. Of note, assessment of data element reliability may not be required by NQF if data element validity is demonstrated.[1324] To assess the validity of new performance measure score (in the case, percentage of COVID–19 vaccination coverage), NQF allows assessment by face validity (that is, subjective determination by experts that the measure appears to reflect quality of care, done through a systematic and transparent process),[1325] and the MAP concurred with the face validity of the COVID–19 Vaccination Coverage among HCP measure. Materials from the March 15, 2021 MAP Coordinating Committee meeting can be found on the NQF website here: *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

This measure is not NQF endorsed, but the CDC, in collaboration with CMS, plans to submit the measure for consideration in the Fall NQF 2021 measure cycle.

(4) Competing and Related Measures

Section 1886(m)(5)(D)(i) of the Act requires that absent an exception under section 1886(m)(5)(D)(ii) of the Act, measures specified under section 1886(m)(5)(D) of the Act be endorsed by the entity with a contract under section 1890(a) of the Act, currently the National Quality Forum (NQF). In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1886(m)(5)(D)(ii) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Section 1899B(e)(2)(A) of the Act requires that, subject to section 1899B(e)(2)(B) of the Act, each measure specified by the Secretary under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a) of the Act. However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The proposed COVID–19 Vaccination Coverage among HCP measure is not currently NQF endorsed and has not been submitted to the NQF for consideration, so we considered whether there are other available measures that assess COVID–19 vaccinations among HCP. After review of the NQF's consensus-endorsed measures, we were unable to identify any NQF-endorsed measures for LTCHs focused on capturing COVID–19 vaccination coverage among HCP, and we found no other feasible and practical measure on the topic of COVID–19 vaccination coverage among HCP. The only other vaccination coverage of HCP measure we found was the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the LTCH QRP in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53630 through 53631).

Given the novel nature of the SARS–CoV–2 virus, and the significant and immediate risk it poses in LTCHs, we believe it is necessary to finalize the measure as soon as possible. Therefore, after consideration of other available measures that assess COVID–19 vaccination rates among HCP, we believe the exception under section 1899B(e)(2)(B) of the Act applies. This measure has the potential to generate actionable data on vaccination rates that can be used to target quality improvement among LTCH providers.

(5) Quality Measure Calculation

The COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in facilities such as LTCHs. Since this measure is a process measure, rather than an outcome measure, it does not require risk-adjustment.

The denominator would be the number of HCP eligible to work in the LTCH for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination described by the CDC.[1326]

The numerator would be the cumulative number of HCP eligible to work in the LTCH for at least 1 day during the reporting period and who received a complete vaccination course against SARS–CoV–2. A complete vaccination course may require one or more doses depending on the specific vaccine used. The finalized measure specifications can be found on the CDC website here: *https://www.cdc.gov/nhsn/nqf/index.html*.

We proposed that LTCHs would submit data for the measure through the CDC/NHSN data collection and submission framework.[1327] This

[1322] The Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS Final Rule (78 FR 47905 through 47906), and in the LTCH QRP in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53630 through 53631).

[1323] Centers for Disease Control and Preventions. Morbidity and Mortality Weekly Report. March 29, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_w*.

[1324] National Quality Form. Key Points for Evaluating Scientific Acceptability. Revised January 3, 2020. *https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Evaluation_Guidance.aspx#:~:text=NQF%20is%20not%20prescriptive%20about,reliability%20or%20validity%20testing%20results.&text=Reliability%20and%20validity%20must%20be,source%20and%20level%20of%20analysis*)

[1325] Ibid.

[1326] Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United Sates. Accessed at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html*.

[1327] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19

Continued

framework is currently used for reporting the CAUTI (NQF #0318) and Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measures. LTCHs would use the COVID–19 vaccination data reporting module in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible who have worked at the facility that week (denominator) and the number of those HCP who have received a completed COVID–19 vaccination course (numerator). LTCHs would submit COVID–19 vaccination data for at least one week each month. If LTCHs submit more than 1 week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the 3 monthly modules reported for the quarter. This quarterly rate would be publicly reported on the Care Compare website. Subsequent to the first refresh, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data on Care Compare.

For purposes of submitting data to CMS for the FY 2023 LTCH QRP, LTCHs would be required to submit data for the period October 1, 2021 through December 31, 2021. Following the initial data submission quarter for the FY 2023 LTCH QRP, subsequent compliance for the LTCH QRP would be based on a full calendar year of data submission. For more information on the measure's proposed public reporting period, we refer readers to section IX.E.9.d. of this final rule.

We invited public comments on our proposal to add a new measure, COVID–19 Vaccination Coverage among Healthcare Personnel, to the LTCH QRP beginning with the FY 2023 LTCH QRP.

Comment: A number of commenters support the proposal to adopt the COVID–19 Vaccination Coverage among HCP measure for the LTCH QRP. A commenter mentioned that the COVID–19 pandemic had a disproportionate and devastating impact on older adults living in congregate care settings and expressed that this measure is vitally important to protect the health and wellbeing of the community, particularly older adults. Commenters agree that the measure would help assess the degree to which LTCHs are taking steps to limit the spread of COVID–19 and reduce the risk of transmission within their facilities. Commenters pointed out that public reporting of COVID–19 vaccination among HCP on Care Compare would provide consumers with important information with which to make informed decisions about the safety of an LTCH. Commenters also believe the information would provide greater transparency to stakeholders seeking to effectively target vaccine hesitancy.

Response: We thank the commenters for their support. We agree that the COVID–19 pandemic has had a disproportionate and devastating impact on older adults living in congregate care settings and that the COVID–19 Vaccination among HCP measure will help assess the degree to which LTCHs are taking steps to limit the spread of COVID–19 and reduce the risk of transmission within their facilities. Consistent with information published by the CDC and others, LTCHs can be high-risk places for COVID–19 exposure and transmission, and COVID–19 can spread among HCP and residents given the close contact that may occur during the provision of care.[1328] Additionally, Medscape Medical News reported on June 28, 2021,[1329] that Federal data show one in four hospital workers across the United States are still unvaccinated, and only one in every three hospital workers are vaccinated in the nation's 50 largest health systems. We agree with commenters that public reporting of COVID–19 Vaccination Coverage among HCP on Care Compare would provide consumers with important information with which to make informed decisions about the safety of an LTCH, and would provide greater transparency to Federal officials and other stakeholders seeking to effectively target vaccine hesitancy.

Comment: We received numerous comments requesting that CMS delay the adoption of the COVID–19 Vaccination Coverage among HCP measure until it has received NQF endorsement. Commenters were concerned that since the measure has not been fully specified, tested, or endorsed by the NQF, then it may not be thoroughly tested and vetted, and may impact patients' certainty that the data they rely on are reliable. Other commenters included language from the Post-Acute Care/Long-term Care Workgroup (Workgroup) of the Measures Application Partnership (MAP) meeting transcript to support their position. They urged the agency, in addition to seeking NQF endorsement, to fully develop and test the measure for reliability and accuracy before implementing it in the LTCH QRP.

Response: Given the novel nature of the SARS–CoV–2 virus, and the significant and immediate health risk it poses in LTCHs, we believe it is necessary to adopt this measure as soon as possible. Additionally, given the results from CDC's preliminary validity testing of the data elements required for the measure numerator (described in Section IX.E.4.a.(3) of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070), the alignment between the denominator of this measure and the denominator of the Influenza Vaccination among HCP (NQF #0431) measure, and the MAP's determination that the COVID–19 Vaccination Coverage among HCP measure has face validity, CMS proposes the COVID–19 Vaccination Coverage among HCP measure beginning with the FY 2023 QRP. As discussed in Section #.E.4.a(4) of this final rule, CMS proposed to adopt this measure without NQF endorsement, as we were unable to identify any NQF-endorsed measures for LTCHs focused on capturing COVID–19 vaccination coverage among HCP, and we found no other feasible and practical measure on the topic of COVID–19 vaccination coverage among HCP. The CDC as the measure steward, in collaboration with CMS, plans to submit the measure for consideration in the Fall NQF 2021 measure cycle.

Comment: In the context of raising concerns about unanswered questions related to COVID–19 vaccines and their potential to affect the appropriateness of this measure, some commenters questioned whether there would be COVID–19 seasons similar to how there are flu seasons. Another commenter stated it is not clear how the COVID–19 ''season'' is defined, or whether it would be associated with the initial vaccination process or potential boosters in the future.

Response: CMS appreciates that there are unanswered questions related to the SARS–CoV–2 virus and COVID–19 vaccinations, including whether COVID–19 seasons may develop similar to the way other human coronaviruses and influenza have seasons. In the event that seasonal COVID–19 patterns emerge, CMS will collaborate with the CDC to determine whether specification

Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

[1328] Chen MK, Chevalier JA, Long EF. Nursing home staff networks and COVID–19. Proceedings of the National Academy of Sciences of the United States of America (PNAS). Available at: *https://www.pnas.org/content/118/1/e2015455118.* Accessed June 29, 2021.

[1329] Medscape. Disturbing Number of Hospital Workers Still Unvaccinated. Available at: *https://www.medscape.com/viewarticle/953871.* Accessed July 13, 2021.

and reporting changes for the COVID–19 Vaccination Coverage among HCP measure are appropriate. In the meantime, CMS believes the current measure specifications appropriately reflect current COVID–19 vaccine recommendations.

Comment: In reaction to CMS' characterization of the alignment between the Influenza Vaccination Coverage among HCP (NQF #0431) measure and the COVID–19 Vaccination Coverage among HCP measure, some commenters raised concerns about specification differences. They believe there are key differences between the two measures, such as how the vaccines are administered and data are collected. Specifically, some commenters pointed out that the Influenza Vaccination Coverage among HCP (NQF #0431) measure utilizes HCP working in the facility for the denominator whereas the proposed COVID–19 metric utilizes HCP eligible to work in the facility.

Response: We acknowledge that there are implementation differences between the two measures, even though the CDC modeled the COVID–19 Vaccination Coverage among HCP measure after the Influenza Vaccination Coverage among HCP (NQF #0413) measure. Nevertheless, the measures are aligned with respect to the reporting mechanism used to report data (that is, NHSN) and key components of the measure specifications (for example, the types of personnel included in the denominator), but still allow for important differences. These differences are necessary to ensure the validity of the COVID–19 Vaccination Coverage among HCP measure, as the administration of the influenza vaccine and the COVID–19 vaccine differ in multiple ways.

The intent of the COVID–19 Vaccination among HCP measure is to include HCP who work regularly in the LTCH. However, many HCP who regularly work in a LTCH may be temporarily absent due to illness, injury, or vacation/leave. Because the measurement period covered by the Influenza Vaccination Coverage among HCP (NQF #0431) measure is quite long (the entire 6 month influenza season), such absences will not impact the Influenza Vaccination Coverage among HCP (NQF #0431) measure denominator. However, the measurement period of the COVID–19 Vaccination among HCP measure is only one week, considerably shorter than the time period covered by the Influenza Vaccination Coverage among HCP (NQF #0431) measure, so a number of regularly working HCP may be absent during this shortened period. Therefore, HCP who regularly work in the LTCH, but may be temporarily absent for up to 2 weeks, are still to be included in the COVID–19 Vaccination among HCP measure. We refer readers to section ##.E.4.a.(5) of this final rule and to the Instructions for Completion of the Weekly Healthcare Personnel COVID–19 Vaccination Cumulative Summary Form for Non-Long-Term Care Facilities (57.220, Rev 3) at *https://www.cdc.gov/nhsn/forms/instr/57.220-toi-508.pdf* which explains how to determine eligible HCP for the measure.

Comment: A commenter questioned whether the COVID–19 Vaccination among HCP measure aligned with the Merit-based Incentive Payment System (MIPS) measure that was reviewed by the MAP and assesses patients who received at least one dose (in addition to a complete course).

Response: We understand the commenter to be inquiring as to whether this measure is similar to the measure considered for another quality reporting program, the Merit-based Incentive Payment System (MIPS) for clinicians. If so, MUC—0045, the SARS–Co–V–2 Vaccination by Clinician measure differs from the COVID–19 Vaccination among HCP measure. Most notably, the SARS–CoV–2 Vaccination by Clinician measure assesses the proportion of patients who received at least one SARS–CoV–2 vaccination while the COVID–19 Vaccination among HCP measure assesses the proportion of HCP who complete a SARS–CoV–2 vaccination course.

Comment: Some commenters submitted comments stating they believe it is premature to begin tracking COVID–19 vaccinations because the COVID–19 vaccines are authorized through an EUA and do not have full FDA approval at this time. Several commenters stated the measure should not be adopted until all existing vaccines authorized under an EUA have received full approval by FDA. Another commenter stated that until FDA approves the vaccines, they do not have control over the vaccination status of their employees.

Response: We disagree with the comment that tracking COVID–19 vaccinations is premature because the vaccines are authorized through an EUA. We believe that due to the continued COVID–19 PHE and the ongoing risk of infection transmission in the LTCH population, the benefits of finalizing this measure in this year's final rule are essential for patient safety. The COVID–19 vaccines are authorized by FDA for widespread use through EUAs. We refer readers to the FDA website for additional information related to FDA's process for evaluating an EUA request at *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained*. Additionally, two of the three vaccines authorized for emergency use are shown to be 90 to 95% effective in preventing COVID–19 in persons without prior infection, and are equally effective across a variety of characteristics, including age, gender, race, ethnicity, and body mass index or presence of other medical conditions.[1330] [1331] In clinical trials, the Pfizer vaccine was 100% effective at preventing severe disease. The third vaccine authorized for emergency use demonstrates it is 93.1% effective at preventing COVID–19 hospitalization and 75% effective against all-cause death.[1332]

The U.S. Equal Employment Opportunity Commission (EEOC) released updated and expanded technical assistance on May 28, 2021.[1333] Specifically, the EEOC stated the Federal equal employment opportunity (EEO) laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations. However, the adoption of this measure does not require that HCP complete a COVID–19 vaccination course. In addition, FDA is closely monitoring the safety of the COVID–19 vaccines authorized for emergency use. Additionally, even if LTCHs have limited control over the vaccination status of their employees, the information collected by this measure is vitally important and useful to stakeholders.

Comment: A commenter stated that if CMS proceeded with finalizing the

[1330] Effectiveness of Pfizer—.

[1331] Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID–19 Among Hospitalized Adults Aged ≥65 Years—United States, January–March 2021. Morbidity and Mortality Weekly Report (MMWR). May 7, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e1.htm?s_cid=mm7018e1_w*. Accessed July 19, 2021.

[1332] The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID–19 Vaccine—United States, February 2021. Morbidity and Mortality Weekly Report (MMWR). March 5, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7009e4.htm*. Accessed July 19, 2021.

[1333] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at: *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws*. Accessed June 25, 2021.

measure, they strongly encourage the agency to consider including all HCP in the denominator, at least for an initial reporting period, to allow for consistent cross-provider reporting and accurate measurement and comparisons. The commenter also stated that if CMS publicly reports this measure, there should be a clear explanation that the measure includes HCP with contraindications.

Response: We interpret the commenter to be stating that the denominator should include HCP with and without contraindication to the vaccination. We believe that excluding HCP with contraindications from the measure strikes an appropriate balance between obtaining accurate estimates of vaccine rates among HCP within LTCHs and not holding an LTCH accountable for HCP with a COVID–19 vaccination contraindication, as the number of HCP with contraindications or exclusions from vaccination is expected to be low.

Comment: Several commenters requested CMS provide clarification about how evolving vaccine recommendations will be accounted for in the COVID–19 Vaccination among HCP measure proposed for the LTCH QRP. A commenter noted that CMS proposed a COVID–19 Vaccination Coverage among HCP measure for the Inpatient Quality Reporting (IQR) program in the FY 2022 Inpatient Prospective Payment System (IPPS)/LTCH proposed rule (86 FR 25573) and stated the numerator would be calculated based on HCP who received a completed vaccination course ''since the vaccine was first available or on a repeated interval if revaccination is recommended.'' They requested CMS provide clarification how evolving vaccine recommendations will be accounted for in the COVID–19 Vaccination among HCP measure proposed for the LTCH QRP. Several commenters specifically questioned how vaccination boosters would factor into reporting requirements. Several commenters believe it would be premature for CMS to adopt the measure because it is unknown how long the COVID–19 vaccination would be effective as well as whether and how often booster shots may be required. Commenters noted that these were important unanswered questions they thought would affect both the design and feasibility of any HCP vaccination measure and would likely result in a change to the measure definition. Several commenters suggested CMS wait until expectations are clarified about maintaining employees' COVID–19 vaccinations.

Response: The COVID–19 Vaccination Coverage among HCP measure is a measure of a completed vaccination course (as defined in Section IX.E.4.a(5) of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070)). A complete vaccination course may require one or more doses depending on the specific vaccine used. Currently, the need for COVID–19 booster doses has not been established, and no additional doses are currently recommended for HCP.[1334] However, we believe that the numerator is sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' and therefore the measure is sufficiently specified to address boosters.

Comment: A couple of commenters expressed concern about unintended consequences and legal risks to their organization if HCP experience an adverse event related to vaccination, and therefore oppose adoption of the COVID–19 Vaccination Coverage among HCP measure into the LTCH QRP.

Response: It is unclear what unintended consequences and legal risks the commenters are referring to. The LTCH QRP is a pay-for-reporting program, and LTCHs are assessed under the program based on whether they have met the LTCH QRP's reporting requirements. The COVID19 Vaccination among HCP measure would not require LTCH HCP to receive the vaccine in order for LTCHs to successfully report the measure. We proposed the COVID–19 Vaccination Coverage among HCP to capture the number of HCP who have received a completed vaccine course.

Comment: A commenter raised concerns that this measure may compel facilities to ensure their employees are vaccinated, and that mandates could be beneficial to measure performance. The commenter pointed out that the decision to implement a mandate in some cases may be beyond providers' control, as multiple states have introduced or passed legislation prohibiting discrimination on COVID–19 vaccination status; other existing state laws might also prohibit mandatory vaccine policies. In practical terms, this could mean that facilities that are unable to mandate COVID–19 vaccines could be at a systematic performance disadvantage on the measure. Another commenter states it would be difficult for providers in some states to accurately collect and report data on vaccination coverage due to new state laws restricting an employer's ability to obtain information regarding an employee's vaccination status. They claim that by adding this measure, CMS would be mandating providers to report data that may be limited due to state restrictions.

Response: Adoption of the COVID–19 Vaccination Coverage among HCP measure into the LTCH QRP would not mandate or require LTCH HCP to complete a COVID–19 vaccination course. It could be the case that LTCHs that do not require their HCP to be vaccinated could have lower vaccination rates than LTCHs that do. However, an LTCH's ability to require vaccines does not make the information provided by this measure any less valuable or important to stakeholders. We believe it is important that LTCHs report the COVID–19 Vaccination Coverage among HCP measure as soon as possible to assess the potential spread of COVID–19 among their HCP and reduce the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of LTCHs to continue serving their communities throughout the PHE and beyond.

Comment: Several commenters raised concerns about factors affecting COVID–19 vaccination rates that they feel are out of their control. For example, some commenters expressed concern over future availability of vaccines, including a commenter who specifically expressed concern over the potential for supply chain disruptions that could impact measure performance through no fault of their own. Another commenter described challenges related to vaccine availability where the LTCH is located and the personal preferences of a facility's staff.

Response: We proposed this measure to provide information to stakeholders about the extent to which HCP have completed a COVID–19 vaccination course during a defined period of time. Factors such as vaccine availability, geographic location, and personal staff preferences ultimately do not make the information captured by this measure any less valuable to stakeholders. However, if an LTCH believes they were disproportionately affected by the PHE, they have the opportunity to apply for an individual exception or extension within 90 days of the date that the extraordinary circumstances occurred as set forth in our regulations at 42 CFR 412.560(c). Instructions for requesting an extraordinary circumstances exemption (ECE) may be found on the LTCH QRP Reconsideration and Exception and Extension web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-*

[1334] Centers for Disease Control and Prevention. Vaccine Administration. Available at: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.* Accessed June 25, 2021.

Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Exception-and-Extension. Additionally, subsequent to the publication of the FY 2022 IPPS/LTCH PPS proposed rule, on April 27, 2021, the White House confirmed that there was sufficient vaccine supply for all Americans.[1335]

Comment: Multiple commenters responded about challenges related to collecting information required for measure reporting. A commenter expressed that their employees' medical records are not kept in the primary electronic health record (EHR), as this is an Occupational Safety and Health Administration (OSHA) violation. They go on to explain that this means they will need to build their own reports to abstract these data. Another commenter noted that some personnel may have received their vaccine outside the facility at mass vaccination sites, and collecting these data across personnel could prove burdensome. Another commenter explained that existing systems do not capture information pertaining to the measure's inclusion criteria, listing COVID–19 vaccine contraindications as an example. The same commenter also has concerns related to challenges providers may have accounting for adult/student trainees and volunteers.

Response: LTCHs have experience tracking information and collecting data to inform their care approaches and business practices. CMS acknowledges there will be initial burden in collecting the information and this is accounted for in Section #.B.7 of this final rule. The data sources for the number of HCP who have received COVID–19 vaccines may include HCP health records and paper and/or electronic documentation of vaccination given at the healthcare facility, pharmacy, or elsewhere. Further, HCP receiving vaccination elsewhere may provide documentation of vaccination. We are confident in LTCHs' abilities to track the COVID–19 vaccination information of their HCP. In addition, as more people become vaccinated, the burden of tracking who has had one or more doses should decline.

Comment: A commenter expressed that a hospital or a person should not be penalized because some people cannot receive vaccines for various reasons, and expressed that it is discrimination to separate the vaccinated from the unvaccinated. The commenter goes on to explain that people need to have choices and do what is best for their health.

Response: The LTCH QRP is a pay-for-reporting program, meaning that penalties are tied to measure reporting and not performance. Additionally, this measure does not separate the vaccinated from the unvaccinated, but rather reports on the proportion of HCP who have completed a COVID–19 vaccination course at a given LTCH during a defined time period. Finally, this measure does not mandate the receipt of COVID–19 vaccines.

Comment: A commenter had a concern with the measure specifications because their healthcare system has some employees that work at three different hospitals within the health care system during any one week period. They requested clarification on how these employees would be reported for purposes of the COVID–19 Vaccination among HCP measure.

Response: The LTCH QRP is distinct and separate from other CMS Quality Reporting Programs, and therefore any HCP that is eligible to work one day during the reporting period in the LTCH is counted for purposes of the COVID–19 Vaccination Coverage among HCP measure, regardless of whether they work in another facility who is also reporting the same measure. Section 1886(m)(5)(F) of the Act requires each LTCH to submit data on resource use and other measures under section 1899(d)(1) of the Act to the Secretary.

Comment: A commenter questioned adopting the measure since they assert that there are remaining unanswered questions they believe affect both the design and feasibility of any HCP vaccination measure, such as how long the vaccines confer immunity.

Response: We acknowledge the science around the SARS–CoV–2 virus continues to evolve. It is another reason the COVID–19 Vaccination Coverage among HCP measure is so important. Population immunity means that enough people in a community are protected from getting a disease because they have already had the disease or because they have been vaccinated. Population immunity makes it hard for the disease to spread from person to person.[1336]

We are still learning how effective the vaccines are against new variants of the virus that cause COVID–19. Current evidence suggests that the COVID–19 vaccines authorized for use in the United States offer protection against most variants currently spreading in the United States.[1337] The CDC will continue to monitor how vaccines are working to see if variants have any impact on how well COVID–19 vaccines work in real-world conditions.

Comment: A commenter is concerned that the proposed measure will create significant implementation challenges and that it may not be feasible for many providers to accurately report on. One reason given for this was that the indications and contraindications for the COVID–19 vaccination have changed at a relatively high frequency, and they are concerned they may continue to change.

Response: The contraindications have not changed. Contraindications are listed in the FDA Fact Sheets [1338] [1339] [1340] and in the Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United States at *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.* Information may be updated based on data from safety monitoring systems at any time. Contraindications and other clinical considerations are accounted for in the COVID–19 Vaccination Coverage among HCP measure.

Comment: A commenter believes the reporting burden of the COVID–19 Vaccination Coverage among HCP measure to be unreasonable for several reasons, including training and revisions to QRP reporting processes, as well as updating IT systems that LTCHs will have to undertake. They state that tracking the Influenza Vaccination Coverage of HCP (NQF #0431) measure

[1335] Press Briefing by White House COVID–19 Response Team and Public Health Officials | The White House

[1336] Centers for Disease Control and Prevention. Population Immunity. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html.* Accessed June 25, 2021.

[1337] Centers for Disease Control and Prevention. COVID–19 vaccines and new variants. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/work.html#:~:text=COVID%2D19%20vaccines%20and%20new%20variants%20of%20the%20virus&text=Current%20data%20suggest%20that%20COVID,after%20they%20are%20fully%20vaccinated.* Accessed June 25, 2021.

[1338] See, *e.g.,* U.S. Food and Drug Administration. (2021). Fact Sheet for Healthcare Providers Administering Vaccine, Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID–19 Vaccine to Prevent Coronavirus Disease 2019 (COVID–19). Available at: *https://www.fda.gov/media/144413/download.*

[1339] See, *e.g.,* U.S. Food and Drug Administration. (2021). Fact Sheet for Healthcare Providers Administering Vaccine, Emergency Use Authorization (EUA) of the Moderna COVID–19 Vaccine to Prevent Coronavirus Disease 2019 (COVID–19). Available at: *https://www.fda.gov/media/144637/download.*

[1340] See, *e.g.,* U.S. Food and Drug Administration. (2021). Fact Sheet for Healthcare Providers Administering Vaccine, Emergency Use Authorization (EUA) of the Janssen COVID–19 Vaccine to Prevent Coronavirus Disease 2019 (COVID–19). Available at: *https://www.fda.gov/media/146304/download.*

across all employees, licensed independent practitioners, adult students and trainees, and volunteers over the age of 18 has been challenging and burdensome, and requiring LTCHs to track COVID–19 vaccination coverage among these same groups is an unreasonable burden when the COVID–19 pandemic is still ongoing.

Response: LTCHs are currently required to submit data for the Influenza Vaccination among HCP measure (NQF #0431) to the CDC's NHSN Healthcare Personnel Safety Component (HPS) annually. While LTCHs will not have the burden of registering and learning how to use the NHSN, we acknowledge there will be burden with collecting the required information. However, we believe it will be minimal because LTCHs already have experience successfully reporting information using the NHSN reporting modules. We refer readers to Section #.B.7. of this final rule for an estimate of burden related to the COVID–19 Vaccination Coverage among HCP measure.

We believe it is important that LTCHs report COVID–19 HCP vaccination rates as soon as possible to assess the potential spread of COVID–19 among their HCP and the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of LTCHs to continue serving their communities throughout the PHE and beyond. Additionally, consistent vaccination reporting by LTCHs via the NHSN will help CMS to identify additional resources and tools LTCHs may need to address the challenges of the PHE.

Comment: A commenter disagreed with the proposal of adopting the COVID–19 Vaccination Coverage among HCP measure to the LTCH QRP, citing the fact that any new measure added to the LTCH QRP creates another basis for CMS to financially penalize LTCHs for even the smallest infractions of the multitudinous guidance documents concerning not only the reporting of the quality data itself, but the many technical elements that need to be perfectly executed in the CDC's NHSN system for that quality data to be processed and transferred to CMS. They feel that providers should never be financially penalized if they report all their quality data by the reporting deadlines, but especially when the quality measure concerns an ongoing global pandemic.

Response: Section 1886(m)(5)(A)(i) of the Act requires the Secretary to apply the 2 percent payment reduction under the LTCH QRP to LTCHs that fail to meet the LTCH QRP reporting requirements during a fiscal year. LTCHs are not financially penalized if they report all their LTCH QRP data by the reporting deadlines.

There are reports available in the Analysis Reports section of NHSN which LTCHs can run to verify their data are complete.[1341] Additionally, CMS' contractor sends informational messages to LTCHs that are not meeting Annual Payment Update (APU) thresholds on a quarterly basis ahead of each submission deadline. Information about how to sign up for these alerts can be found on the LTCH QRP Help web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Help*.

Comment: A commenter did not support the proposed COVID–19 Vaccination Coverage among HCP measure because it only excludes patients who do not get a COVID–19 vaccine due to medical contraindications. They state that since the EEOC requires employers to provide a reasonable accommodation if an employee's sincerely held religious belief, practice or observance prevents them from receiving the vaccination, the EEOC policy conflicts with the specifications of the proposed measure.

Response: We believe the commenter is referring to the updated and expanded technical assistance the EEOC issued on May 28, 2021.[1342] CMS disagrees that the proposal conflicts with the EEOC's guidance. Specifically the EEOC stated the EEO laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations. This measure would report the number of HCP who have received a COVID–19 vaccination, but it does not require LTCH HCP to receive a COVID–19 vaccination.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal as proposed to adopt the COVID–19 Vaccination Coverage among HCP measure to the LTCH QRP beginning with the FY 2023 LTCH QRP.

[1341] Detailed guidance can be found at: *https://www.cdc.gov/nhsn/cms/index.html*. If you have questions regarding these reports within NHSN, please contact the NHSN Help Desk at *NHSN@cdc.gov*.

[1342] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at: *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws*. Accessed June 25, 2021.

b. Update to the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure Beginning With the FY 2023 LTCH QRP

We proposed to update the Transfer of Health Information to the Patient—Post-Acute Care (PAC) measure denominator to exclude patients discharged home under the care of an organized home health service or hospice. This measure assesses for and reports on the timely transfer of health information, specifically transfer of a medication list. We adopted this measure in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42525 through 42535) beginning with the FY 2022 LTCH QRP. It is a process measure that evaluates the transfer of information when a patient is discharged from his or her current PAC setting to a private home/apartment, board and care home, assisted living, group home, transitional living, or home under the care of an organized home health service organization or hospice.

This measure, adopted under section 1899B(c)(1)(E) of the Act, was developed to be a standardized measure for the IRF QRP, LTCH QRP, SNF QRP and Home Health (HH) QRP. The measure is calculated by one standardized data element that asks, ''At the time of discharge, did the facility provide the patient's current reconciled medication list to the patient, family, and/or caregiver?'' The discharge location is captured by items on the Long-Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS).

Specifically, we are proposed to update the measure denominator. Currently, the measure denominators for both the TOH-Patient measure and the TOH-Provider measure assess the number of patients discharged home under the care of an organized home health service organization or hospice. In order to align the measure with the SNF QRP, IRF QRP, and HH QRP, and avoid counting the patient in both TOH measures in the LTCH QRP, we proposed the removal of this location from the definition of the denominator for the TOH-Patient measure. Therefore, we proposed to update to the denominator for the TOH-Patient measure to only discharges to a private home/apartment, board and care home, assisted living, group home, or transitional living. For additional technical information regarding the TOH-Patient measure, we refer readers to the document titled ''Final Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements available at *https://www.cms.gov/Medicare/Quality-*

Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Final-Specifications-for-LTCH-QRP-Quality-Measures-and-SPADEs.pdf.

We invited public comments on our proposal to update the denominator of the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure beginning with the FY 2023 LTCH QRP.

Comment: We received overwhelming support for our proposal to update the TOH-Patient-PAC measure's denominator to remove the inclusion of ''home under care of an organized home health service organization or hospice.'' Commenters agreed that the update will reduce denominator redundancy in the two TOH Information—PAC measures. A commenter mentioned that this update will increase the usefulness of both the TOH-Patient-PAC and TOH-Provider-PAC measures because the same patients will not be counted in both measures. Another commenter noted their appreciation of CMS' continued review of measures used in its various Medicare QRPs to make changes that mitigate unnecessary provider burden.

Response: We appreciate the commenters' support, and agree that this update removes redundancy between the TOH-Patient-PAC and TOH-Provider-PAC measures, and reduces burden.

Comment: A commenter noted their support for our proposal to update the TOH-Patient-PAC measure, but also recommended that CMS remove short stays (for example less than 5 days) from all LTCH QRP measures.

Response: While this comment is out of scope, we would like to clarify that CMS carefully considers length of stay when developing quality measures. For example, stays less than three days long are excluded from the Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilation Support measure (NQF #2632) because it would typically not allow sufficient time to collect all of the items or for a patient to demonstrate a meaningful change. We agree that it may be more challenging to acquire and transfer medication information for patients with shorter lengths of stay, but maintain our believe that this is critically important for all patients regardless of stay length, and especially important for patients who are discharged for emergent reasons.

Final Decision: After careful consideration of the public comments we received, we are finalizing our proposal as proposed to update the denominator for the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure beginning with the FY 2023 LTCH QRP.

5. LTCH QRP Quality Measures Under Consideration for Future Years: Request for Information

We sought input on the importance, relevance, appropriateness, and applicability of each of the measures and concepts under consideration listed in Table FF2 for future years in the LTCH QRP.

TABLE FF2: FUTURE MEASURES AND MEASURE CONCEPTS UNDER CONSIDERATION FOR THE LTCH QRP

Assessment-Based Quality Measures and Measure Concepts
Frailty
Opioid use and frequency
Patient reported outcomes
Shared decision making process
Appropriate pain assessment and pain management processes
Malnutrition
Health equity

We received several comments on this RFI, which are summarized below:

Comment: Several commenters supported the inclusion of most of the proposed measures listed in Table FF2. A commenter said they were concerned that most of these metrics are not valid for LTCHs, and believes they should first be initiated in the short stay hospital where baseline information can be obtained and then LTCHs could add to the patient's continuing care record. This commenter also questioned whether an LTCH has any ability to impact these metrics during a patient's LTCH stay.

A commenter thought the most significant opportunity from the proposed list was the concept of measuring malnutrition, and said there should be significant efforts to identify patients that have clinical diagnoses associated with being malnourished. Another commenter said that while malnutrition and frailty, are important factors in patient clinical and utilization outcomes, they did not think LTCHs were likely to reverse patient malnutrition or frailty as a clinical outcome within the timespan of one admission. Several commenters thought frailty would be more appropriate as a risk-adjustment variable or used in stratified reporting of measure results, and recommended that CMS not implement it as a process of care measure.

A few commenters stated that the concept of shared decision-making may be more appropriately assessed at the clinician-level than the hospital level.

We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to this Request for Information in this final rule, we intend to use this input to inform our future measure development efforts.

6. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Quality Programs—Request for Information (RFI)

a. Solicitation of Comments

We sought input on the following steps that would enable transformation of CMS' quality measurement enterprise to be fully digital:

i. What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?

ii. How do you currently share information with other providers?

iii. In what ways could we incentivize or reward innovative uses of health information technology (IT) that could reduce burden for post-acute care settings, including but not limited to LTCHs?

iv. What additional resources or tools would post-acute care settings, including but not limited to LTCHs, and health IT vendors find helpful to support the testing, implementation, collection, and reporting of all measures using FHIR standards via secure APIs to reinforce the sharing of patient health information between care settings?

v. Would vendors, including those that service post-acute care settings, such as LTCHs, be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would align standards for quality measure data collection across care settings to improve care coordination, such as sharing patient data via secure FHIR API as the basis for calculating and reporting digital measures?

We received a number of comments and appreciate the time commenters took to respond. We plan to continue working with other agencies and stakeholders to coordinate and to inform our transformation to dQMs leveraging health IT standards. We will consider all input as we develop future LTCH QRP proposals and future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

7. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs—Request for Information (RFI)

a. Solicitation of Public Comment

Under the authority of the IMPACT Act and section 1886(m)(5) of the Act, we sought comment on the possibility of revising measure development, and the collection of other Standardized Patient Assessment Data Elements that address gaps in health equity in the LTCH QRP. Any potential data collection or measure reporting related to health equity within a CMS program, including the LTCH QRP that might result from public comments received in response to this solicitation would be addressed through a separate notice-and-comment rulemaking in the future.

Specifically, we are invited public comment on the following:

- Recommendations for quality measures, or measurement domains that address health equity, for use in the LTCH QRP.
- As finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42577 through 42588), LTCHs must report certain Standardized Patient Assessment Data Elements on SDOH, including race, ethnicity, preferred language, interpreter services, health literacy, transportation and social isolation.[1343] CMS sought guidance on any additional Standardized Patient Assessment Data Elements that could be used to assess health equity in the care of LTCH patients, for use in the LTCH QRP.
- Recommendations for how CMS can promote health equity in outcomes among LTCH patients. For example, we are interested in feedback regarding whether including facility-level quality measure results stratified by social risk factors and social determinants of health (for example, dual eligibility for Medicare and Medicaid, race) in confidential feedback reports could allow facilities to identify gaps in the quality of care they provide. (For example, methods similar or analogous to the CMS Disparity Methods [1344] which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures, which are currently included in the Hospital Readmission Reduction Program (see 84 FR 42496 through 42500)).
- Methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.
- Given the importance of structured data and health IT standards for the capture, use, and exchange of relevant health data for improving health equity, the existing challenges LTCHs encounter for effective capture, use, and exchange of health information, including data on race, ethnicity, and other social determinants of health, to support care delivery and decision making.

While we will not be responding to specific comments submitted in response to this Health Equity RFI in this final rule, we appreciate all of the comments and interest in this topic. We will continue to take all concerns, comments, and suggestions into account as we continue work to address and develop policies on this important topic. It is our hope to provide additional stratified information to providers related to race and ethnicity if feasible. The provision of stratified measure results will allow PAC providers to understand how they are performing with respect to certain patient risk groups, to support these providers in their efforts to ensure equity for all of their patients and to identify opportunities for improvements in health outcomes.

8. Form, Manner, and Timing of Data Submission Under the LTCH QRP

a. Background

We refer readers to the regulatory text at 42 CFR 412.560(b) for information regarding the current policies for reporting LTCH QRP data.

b. Schedule for Data Submission of the COVID–19 Vaccination Coverage Among Healthcare Personnel Measure Beginning With the FY 2023 LTCH QRP

As discussed in section IX.E.4.a. of this final rule, we proposed to adopt the COVID–19 Vaccination Coverage among HCP measure beginning with the FY 2023 LTCH QRP. Given the time-sensitive nature of this measure in light of the PHE, we proposed an initial data submission period from October 1, 2021 through December 31, 2021. Starting in CY 2022, LTCHs would be required to submit data for the entire calendar year beginning with the FY 2024 LTCH QRP.

LTCHs would submit data for the measure through the CDC/NHSN web-based surveillance system. LTCHs currently utilize the NHSN for purposes of meeting other LTCH QRP requirements.[1345] LTCHs would use the COVID–19 vaccination data collection module in the NHSN Healthcare Personnel Safety (HPS) Component to report the cumulative number of HCP eligible to work in the LTCH for at least 1 day during the reporting period, excluding persons with contraindications to COVID–19 vaccination (denominator) and the cumulative number of HCP eligible to work in the LTCH for at least 1 day during the reporting period and who have received a complete vaccination course against COVID–19 (numerator). LTCHs would submit COVID–19 vaccination data through the NHSN for at least 1 week each month and the CDC would report to CMS quarterly.

We invited public comments on this proposal.

Comment: Several commenters expressed concerns about the

[1343] In response to the COVID–19 PHE, CMS released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the SDOH for at least one full fiscal year after the end of the PHE.

[1344] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

[1345] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

administrative burden associated with reporting of the COVID–19 Vaccination Coverage among Healthcare Personnel measure through NHSN as well as other systems, referring to the Department of Health and Human Services TeleTracking system, and various state agencies and databases. They stated that having to utilize these systems in addition to the NHSN is redundant and burdensome, and requires additional staff to meet the current demands for reporting COVID–19 information. They urged CMS to use data from these other systems without requiring additional data collection in the NHSN.

Response: The TeleTracking system was one system used by the Federal Government to manage the critical first months of the COVID–19 PHE, as it was critical that the Federal Government receive data to facilitate planning, monitoring, and resource allocation during the COVID–19 PHE. The TeleTracking system collects a number of data points, such as ventilators in the facility, ventilators in use, ICU beds available and ICU beds occupied, but providers, including LTCHs, are not required to report data to the TeleTracking system for the LTCH QRP. We have proposed to use the NHSN COVID–19 Modules for tracking COVID–19 vaccination coverage among HCP across all sites of service, including for the LTCH QRP because the Tele-Tracking system does not collect the information needed to calculate the COVID–19 Vaccination coverage among HCP, and because LTCHs currently utilize the NHSN for reporting data on the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138), the NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139), the NHSN Facility-Wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717), and the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure.

However, we do recognize that this measure may lead to duplicative reporting requirements if LTCHs voluntarily report COVID–19 HCP vaccination information to data reporting systems other than the NHSN, and we are collaborating with other HHS agencies, including the CDC, to ensure minimal reporting burden and to eliminate duplicative requirements to the extent feasible.

Comment: Several comments were submitted questioning CMS' statement that the COVID–19 Vaccination Coverage among HCP measure was modeled after the Influenza vaccination among HCP (NQF #0431) measure. A commenter stated it was not clear why there would be multiple time frames associated with the COVID–19 Vaccination Coverage among HCP measure, rather than the submission frequency for the Influenza Vaccination among HCP (NQF #0431) measure which is only one time per year. This commenter suggested that if CMS were to adopt this COVID–19 Vaccination Coverage among HCP measure, that an organization submit its compliance one time for the identified period.

Response: We are interpreting the commenter's reference to multiple time frames to refer to the one week per month proposed data submission frequency. We agree that there are key differences between the Influenza Vaccination among HCP measure and the COVID–19 Vaccination Coverage among HCP measure. We acknowledge that even though the CDC modeled the COVID–19 Vaccination Coverage among HCP measure after the Influenza Vaccination among HCP measure, the influenza vaccine and the COVID–19 vaccine are not identical. The measures are aligned with respect to the reporting mechanism used to report data (the NHSN) and key components of the measure specifications (for example, the definition of the denominator), but the measures allow for important differences to reflect the reality that the circumstances around vaccine administration are not identical. We proposed a reporting schedule for the COVID–19 Vaccination Coverage among HCP measure of 1 week per month to provide vaccination coverage data on a more timely basis than the Influenza Vaccination Coverage among HCP measure (NQF #0431), while also reducing the burden on LTCHs that weekly reporting of this information would have created.

Comment: Several commenters disagreed with the measure submission frequency, stating that CMS should revise the methodology associated with the frequency of data collection for this measure because they believe data from one day each month is a sufficient snapshot of COVID–19 vaccination rates for a LTCH's HCP. They went on to say that the time and resources required by LTCHs to report the data one week a month creates an undue burden on LTCHs during the PHE.

Response: We developed the COVID–19 Vaccination Coverage among HCP measure to align with the Influenza Vaccination among HCP (NQF #0431) measure. However, we proposed that LTCHs report the measure one week per month to provide vaccination coverage data on a more timely basis than the Influenza Vaccination among HCP (NQF #0431) measure while also reducing burden on LTCHs. Additionally a weekly reporting period has been the reporting cycle for many COVID–19-related metrics during the pandemic.

Final Decision: After careful consideration of the public comments we received, we are finalizing as proposed the schedule for data submission of the COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the FY 2023 SNF QRP.

9. Policies Regarding Public Display of Measure Data for the LTCH QRP

a. Background

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public, including the performance of individual LTCHs, after ensuring that LTCHs have the opportunity to review their data prior to public display. LTCH QRP measure data are currently displayed on the *Long-term care hospitals* website within Care Compare and the Provider Data Catalog, which are CMS websites. Both Care Compare and the Provider Data Catalog replaced LTCH Compare and Data.Medicare.gov, which were retired in December 2020. For a more detailed discussion about our policies regarding public display of LTCH QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231 through 57236).

b. Publicly Report the Compliance With Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay Measure Beginning With the FY 2023 LTCH QRP

We proposed public reporting for the Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure beginning with the March 2022 Care Compare refresh or as soon as technically feasible using four rolling quarters of discharge data collected in Q3 2020 through Q2 2021 (July 1, 2020 through June 30, 2021) for the inaugural display of this measure. We proposed publicly reporting the Compliance with SBT by Day 2 of the LTCH Stay measure for data collected from July 1, 2018 through December 31, 2019 on CMS' Provider Data Catalog (PDC) web page. We adopted the Compliance with SBT by Day 2 of the LTCH Stay measure in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38439 through 38446). Data collection for this assessment-based measure began with patients admitted and discharged on or

after July 1, 2018. To ensure the statistical reliability of the data, we proposed not to publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases [1346] during each performance period. LTCHs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/patient stays is too small to publicly report.''

LTCHs were required to collect and submit data for the Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure beginning on July 1, 2018 (Q3 2018), six calendar year quarters prior to the data proposed for the inaugural display of the measure on Care Compare. The first quarter of data collected and submitted by LTCHs (that is, Q3 2018) will be nearly 3.5 years old at that time. Therefore, CMS believes it is in the best interest of providers and the public to use the most recent available four quarters of data (that is, July 1, 2020 through June 30, 2021) for the inaugural public display of the Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure on Care Compare and to post provider performance on the Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure using the older data (that is, July 1, 2018 through December 31, 2019) on CMS' Provider Data Catalog (PDC) web page (*https://data.cms.gov/provider-data/*).

We invited public comments on the proposal to publicly display the measure, Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure on Care Compare and PDC.

Comment: We received two comments supporting the proposed public reporting of the SBT by Day 2 of the LTCH Stay measure. A commenter stated that because LTCHs have been measuring these data since 2018, and some even longer than that, it would not be onerous to use 4 quarters of the most recent data for public reporting in the March 2022 Care Compare refresh.

Response: We thank the commenters for their support, and agree that because the SBT by Day 2 of the LTCH Stay measure is not new, and LTCHs have the ability to access their QM feedback reports, they have had information to help them improve their SBT strategies, and better understand their own LTCH's SBT rate compared to other LTCHs and the national average.

Comment: We received a comment raising several concerns about the SBT by Day 2 of the LTCH Stay measure specifications, including the timeframe for the measure, administrative burden and the multi-component structure of the measure. Additionally, the commenter stated the measure might have the unintended consequence of pressuring clinicians to make a judgment without enough information, and encouraged the agency to perform a meta-analysis of the SBT by Day 2 of the LTCH Stay measure if it had not yet done so.

Response: The SBT by Day 2 of the LTCH Stay measure was finalized in the FY 2018 IPPS/LTCH PPS Final Rule (82 FR 38443), and CMS did not propose changes to the measure specifications in the 2022 IPPS/LTCH PPS (86 FR 25070) proposed rule. Therefore, we will not be responding to those comments here, but will take these comments into consideration for potential refinements in the future.

Regarding unintended consequences, we interpret the commenter to mean that publicly reporting the SBT by Day 2 of the LTCH Stay measure might pressure clinicians to make a judgment without enough information, which could negatively impact patient outcomes. We appreciate the commenters' concerns pertaining to patient safety, and would like to emphasize that patient safety is a top priority. We encourage LTCHs to use best patient care practices when assessing patients for readiness for ventilator liberation. In addition, we note that while the measure assesses LTCHs on completing an assessment of the patient to determine whether patient is medically ready to be liberated from mechanical ventilation, it does not require providers to make any particular assessment, and we encourage providers to classify patients as ''weaning'' or ''non-weaning'' as clinically appropriate. Of note, evidence-based guidelines emphasize that after a commonsense clinical assessment, the best approach to determining readiness for ventilator discontinuation is an SBT,[1347] and that the most effective method of liberation follows a systematic approach that includes a daily assessment of weaning readiness, in conjunction with spontaneous breathing trials.[1348] If a clinician deems a patient medically unready to perform SBT, then the decision should documented and LTCHs should code this item appropriately.

Finally, CMS regularly monitors the performance for all measures submitted for purposes of the LTCH QRP to identify unintended consequences, and should they arise makes measure modifications as appropriate.

Comment: Several commenters stated they do not support CMS' proposal to publicly report LTCH QRP data that was collected by LTCHs during the COVID–19 PHE. They noted that even after July 1, 2020, many parts of the country were experiencing their highest rates of COVID–19 infections rather than during Q1 and Q2 of 2020 when the QRP reporting exception was in effect.

Response: We interpret the commenters to be referring to both the SBT by Day 2 of the LTCH Stay measure and the VLR measure, and will respond to the comment for both measures here.

We believe that the unprecedented risks associated with the COVID–19 PHE warrant direct attention. COVID–19 caused severe respiratory symptoms including acute respiratory distress syndrome (ARDS), which can progress to acute respiratory failure (ARF). A recent study found an increase of approximately 3% annually in the last five years of mortality due to respiratory failure. Additionally the number of deaths from ARDS, which had been declining in the U.S., is now stagnant. The incidence of mortality due to acute respiratory failure (ARF) and ARDS is also higher in rural areas and among non-Hispanic black persons.[1349] Data also shows that eight out of every 10 deaths related to COVID–19 have been in adults 65 years of age and older. When compared to 18- to 29-year-olds, adults over 65 have five to eight times higher risk of being hospitalized from COVID–19 and those older than 75 have 220 times higher risk of dying.[1350] Moreover, many common chronic conditions raise the risks associated with contracting COVID–19, including hypertension, obesity, chronic obstructive pulmonary disease, heart disease, diabetes, and chronic kidney

[1346] We define an ''eligible case'' as a case that meets all of the criteria under the measure's denominator, which can be found In the LTCH QRP Measure Calculations and Reporting Manual found on the LTCH QRP Measures Information web page here: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.*

[1347] Hess DR, et al. Ventilator Discontinuation: Why Are We Still Weaning? *American Journal of Respiratory and Critical Care Medicine,* 184(4), pp. 392–394.

[1348] Haas CF, Loik PS. Ventilator discontinuation protocols. *Respir Care.* 2012 Oct;57(10):1649–63. Accessed July 1, 2021.

[1349] Parcha V, Kalra R, Bhatt, SP, et al. Trends and Geographic Variation in Acute Respiratory Failure and ARDS Mortality in the United States.

[1350] National Institute for Health Care Management (NIHCM). Aging & COVID–19: Vaccination, Mental and Physical Health, and Isolation. Updated February 17, 2021. Available at: *https://nihcm.org/publications/aging-covid-19-vaccination-mental-and-physical-health-and-isolation.* Accessed June 26, 2021.

disease.[1351] The COVID–19 pandemic was expected to result in an increased utilization of mechanical ventilation, and in recently conducted routine monitoring of its measures, CMS found evidence consistent with this expectation where the number of patients who were admitted to a LTCH on mechanical ventilation increased 7.5% since Q3 of 2019.

Therefore we do not believe delaying the public reporting of the SBT by Day 2 of the LTCH Stay measure and the VLR measure is in the public's best interest. We believe that publicly reporting the SBT by Day 2 of the LTCH Stay and VLR measures on Care Compare can assist consumers by providing more recent quality data as well as more actionable data for LTCH providers.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to publicly report the Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay Measure on Care Compare and PDC.

c. Publicly Report the Ventilator Liberation Rate for the PAC LTCH QRP Measure Beginning With the FY 2023 LTCH QRP

We proposed public reporting for the Ventilator Liberation Rate for the PAC LTCH QRP measure, beginning with the March 2022 Care Compare refresh or as soon as technically feasible using four rolling quarters of discharge data collected in Q3 2020 through Q2 2021 (July 1, 2020 through June 30, 2021) for the inaugural display of this measure. We proposed publicly reporting the Ventilator Liberation rate for the PAC LTCH QRP measure for data collected from July 1, 208 through December 31, 2019 on CMS' Provider Data Catalog (PDC) web page. We adopted the Ventilator Liberation Rate measure in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38439 through 38446). Data collection for this assessment-based measure began with patients admitted and discharged on or after July 1, 2018. To ensure the statistical reliability of the data, we proposed not to publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases during each performance period. LTCHs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/patient stays is too small to publicly report.''

LTCHs were required to collect and submit data for the Ventilator Liberation Rate for the PAC LTCH QRP measure beginning on July 1, 2018 (Q3 2018), 6 calendar year quarters prior to the data proposed for the inaugural display of the measure on Care Compare. The first quarter of data collected and submitted by LTCHs (that is, Q3 2018) will be nearly 3.5 years old at that time. Therefore, CMS believes it is in the best interest of providers and the public to use the most recent available four quarters of data (that is July 1, 2020 through June 30, 2021) for the inaugural public display of the Ventilator Liberation Rate for the PAC LTCH QRP measure on Care Compare and to post provider performance on the Ventilator Liberation Rate for the PAC LTCH QRP measure using the older data (that is, July 1, 2018 through December 31, 2019) on CMS' Provider Data Catalog (PDC) web page (*https://data.cms.gov/provider-data/*).

We invited public comments on the proposal to publicly display the measure, Ventilator Liberation Rate for the PAC LTCH QRP on Care Compare and PDC.

Comment: We received two comments in support of the proposed public reporting of the Ventilator Liberation Rate (VLR) for the PAC LTCH QRP measure. A commenter stated that because LTCHs have been reporting this data to CMS since 2018, and some even longer than that, it would not be onerous to use 4 quarters of the most recent data for public reporting in the March 2022 Care Compare refresh.

Response: We thank the commenters for their support, and agree that the VLR measure is not new. LTCHs have the ability to access their QM feedback reports, so they have had information to help them improve their care approaches to achieve higher VLRs, and better understand their own LTCH's VLR rate compared to other LTCHs and the national average.

Comment: Several commenters stated they do not support CMS' proposal to publicly report LTCH QRP data that was collected by LTCHs during the COVID–19 PHE. They noted that even after July 1, 2020, many parts of the country were experiencing their highest rates of COVID–19 infections rather than during Q1 and Q2 of 2020 when the QRP reporting exception was in effect.

Response: We interpret the commenters to be referring to both the SBT by Day 2 of the LTCH Stay measure and the VLR measure. We disagree with the commenter and believe that the unprecedented risks associated with the COVID–19 PHE warrant direct attention, especially given the evidence CMS found in recently conducted routine monitoring of its measures where the number of patients who were admitted to a LTCH on mechanical ventilation increased 7.5% since Q3 of 2019. While we understand that there are concerns related to the use of Q3 and Q4 2020 data and subsequent quarters, we do not believe that further exempting providers from LTCH QRP reporting requirements, nor the continued suspension of public reporting, are actionable solutions. We granted a 6-month exception to LTCH QRP reporting requirements due to the PHE under 42 CFR 412.560(c)(4)(i) of our regulations for Q1 and Q2 of 2020, a sufficient timeframe for LTCHs to adjust to the change in care patterns associated with the pandemic. We further believe that the public display of quality data is extremely important so patients and caregivers can continue to make informed healthcare choices. More details can be found in section ##.E.9.b of this final rule.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal as proposed to publicly report the Ventilator Liberation Rate for the PAC LTCH QRP on Care Compare and PDC.

d. Publicly Report the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2023 LTCH QRP

We proposed to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the September 2022 Care Compare refresh or as soon as technically feasible using data collected for Quarter 4 2021 (October 1, 2021 through December 31, 2021). If finalized as proposed, a LTCH's HCP COVID–19 vaccination coverage rate would be displayed based on one quarter of data. Provider preview reports would be distributed in June 2022. Subsequent to the September 2022 Care Compare refresh, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four quarters of data is reached. Thereafter, the measure would be publicly reported using four rolling quarters of data.

We invited public comments on this proposal for the public display of the measure, COVID–19 Vaccination Coverage among HCP on Care Compare.

Comment: A commenter supported the proposed adoption of the COVID–19 Vaccination Coverage among HCP measure to monitor vaccination rates among HCP in LTCHs because requiring facilities to report COVID–19

[1351] Centers for Disease Control and Prevention. Science Brief: Evidence used to update the list of underlying medical conditions that increase a person's risk of severe illness from COVID–19. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html*. Accessed June 26, 2021.

Vaccination Coverage among HCP rates would provide greater transparency to Federal officials and other stakeholders seeking to effectively target vaccine hesitancy and resources related to the COVID–19 vaccines. They also believe that publishing facility-level data on HCP vaccination rates would provide additional information about facilities' pandemic response and readiness efforts.

Response: We thank the commenter for their support and agree that vaccinations are a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[1352] The CDC has emphasized that health care settings, including LTCHs, can be high-risk places for COVID–19 exposure and transmission.[1353]

Comment: Several commenters voiced their concern about publicly reporting the COVID–19 Vaccination Coverage among HCP measure. While many of them voiced their support of the right of consumers to access real-time meaningful data to help inform healthcare decision-making, they believe the use of a single, dated measure is not a true reflection of the safety or quality of care delivered at an LTCH since vaccines are just one tactic for preventing and controlling COVID–19 infections.

Response: CMS believes it is important to make the most up-to-date data available to beneficiaries, which will support them in making essential decisions about health care. Based on these concerns, we will revise the public reporting policy for this measure to use quarterly reporting, as opposed to averaging over four rolling quarters, which allows the most recent quarter of data to be displayed. This revision would result in publishing information that is more up to date and would not affect the data collection schedule established for submitting data to NHSN for the COVID–19 Vaccination Coverage among HCP measure. This revision would simply update the way the measure's data are displayed for public reporting purposes.

Comment: Commenters were concerned that if CMS adopted the COVID–19 Vaccination among HCP measure, then the data will be publicly displayed on Care Compare without proper context, and they are concerned the public will not understand the information concerning the FDA's EUA process as well as the legal questions LTCHs faced about whether they could impose vaccination requirements as a condition of employment.

Response: It is unclear what legal questions the commenters are referring to, but we assume they are related to requiring vaccination. As discussed in section #.E.4.a.(5) of this final rule, the COVID–19 Vaccination among HCP measure does not require LTCHs to vaccinate their HCP. In addition, we believe staff vaccination rates are essential information for consumers that are activity making decisions about where to seek care. While we understand there are concerns related to the vaccine's FDA authorization and the inability to require their HCP to receive a COVID–19 vaccination, the COVID–19 vaccinations are authorized by the FDA for widespread use through EUAs.

Comment: Commenters supportive of using the TeleTracking system to report vaccination information in lieu of the NHSN also urged CMS to direct consumers to use the TeleTracking system to find LTCH's performance on the COVID–19 Vaccination Coverage among HCP measure, instead of Care Compare.

Response: We disagree. The Care Compare tool provides a user-friendly interface that patients and caregivers can use to make informed decisions about healthcare based on cost, quality of care, volume of services, and other data, while also giving patients and caregivers the option to compare LTCHs using this information. The data found in the TeleTracking system does not have these features.

Comment: Several commenters did not support the proposal to use a shortened reporting timeframe of October 2021–December 2021 to meet the APU reporting requirements for the FY 2023.

Response: We interpret the comment to be about the LTCH QRP reporting requirements to meet the compliance threshold for the FY 2023 Annual Payment Update (APU). Our proposal to use of one quarter of data for the initial year of quality reporting for a new measure is consistent with the approach finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49326 to 49843) for all new measures in their first year of data reporting.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the September 2022 Care Compare refresh or as soon as technically feasible based on data collected for Q4 2021 (October 1, 2021 through December 31, 2021). However, in response to public comment, we will not finalize our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. We will instead only report the most recent quarter of data.

e. Public Reporting of Quality Measures in the LTCH QRP With Fewer Quarters Due to COVID–19 Public Health Emergency (PHE) Exemption

(1) COVID–19 Public Health Emergency Temporary Exemptions

Under the authority of section 319 of the Public Health Service Act, the Secretary declared a public health emergency (PHE) effective as of January 27, 2020. On March 13, 2020, subsequent to a presidential declaration of national emergency under the Stafford Act, the Secretary invoked Section 1135(b) of the Act (42 U.S.C. 1320b–5) to waive or modify the requirements of titles XVIII, XIX, and XXI of the Act and regulations related to the PHE for COVID–19 effective as of March 1, 2020.[1354] On March 27, 2020, we sent a guidance memorandum under the subject title, ''Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19'' to the Medicare Learning Network (MLN) Connects Newsletter and Other Program-Specific Listserv Recipients,[1355] hereafter referred to as the March 27, 2020 CMS Guidance Memo. In that memo we granted an exception to the LTCH QRP reporting requirements from Q4 2019 (October 1, 2019–December 31, 2019) Q1 2020 (January 1, 2020–March 31, 2020) and Q2 2020 (April 1, 2020–June 30, 2020). We also stated that we would not publicly report any LTCH QRP data that might be greatly impacted by the

[1352] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[1353] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[1354] *https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.*

[1355] *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

exceptions from Q1 and Q2 of 2020. This exception impacted the schedule for public reporting that would have included those two quarters of data.

LTCH QRP measures are publicly reported on Care Compare. Care Compare uses four quarters of data for LCDS assessment-based measures, with the exception of the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients requiring Ventilator Support (NQF #2632) which uses eight quarters of data. Care Compare uses eight quarters of data for claims based measures. Table FF3 displays the original schedule for public reporting of LTCH QRP measures.[1356]

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[1356] More information about the LTCH QRP Public Reporting schedule can be found on the LTCH QRP Public Reporting website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Public-Reporting.*

TABLE FF3. LTCH QRP QUARTERS IN CARE COMPARE ORIGINAL SCHEDULE FOR REFRESHES AFFECTED BY COVID-19 PHE EXEMPTIONS - ASSESSMENT AND CLAIMS BASED MEASURES

Quarter Refresh	LTCH QRP Quarters in Original Schedule for Care Compare
Actual December 2020 (on Care Compare)	LCDS: Q1 2019 – Q4 2019 (4 quarters)* LCDS Mobility Measure: Q1 2018 – Q4 2019 (8 quarters)* Claims: Q4 2017 – Q3 2019 (8 quarters)
Original December 2020	LCDS: Q2 2019 – Q1 2020 (4 quarters) LCDS Mobility Measure: Q2 2018 – Q1 2020 (8 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
March 2021	LCDS: Q3 2019 – Q2 2020 (4 quarters) LCDS Mobility Measure: Q3 2018 – Q2 2020 (8 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
June 2021	LCDS: Q4 2019 – Q3 2020 (4 quarters) LCDS Mobility Measure: Q4 2018 – Q3 2020 (8 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
September 2021	LCDS: Q1 2020 – Q4 2020 (4 quarters) LCDS Mobility Measure: Q1 2019 – Q4 2020 (8 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
December 2021	LCDS: Q2 2020 – Q1 2021 (4 quarters) LCDS Mobility Measure: Q2 2019 – Q1 2021 (8 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
March 2022	LCDS: Q3 2020 – Q2 2021 (4 quarters) LCDS Mobility Measure: Q3 2019 – Q2 2021 (8 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
June 2022	LCDS: Q4 2020 – Q3 2021 (4 quarters) LCDS Mobility Measure: Q4 2019 – Q3 2021 (8 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
September 2022	LCDS: Q1 2021 – Q4 2021 (4 quarters) LCDS Mobility Measure: Q1 2020 – Q4 2021 (8 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
December 2022	LCDS: Q2 2021 – Q1 2022 (4 quarters) LCDS Mobility Measure: Q2 2020 – Q1 2022 (8 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
March 2023	LCDS: Q3 2021 – Q2 2022 (4 quarters) LCDS Mobility Measure: Q3 2020 – Q2 2022 (8 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
June 2023	LCDS: Q4 2021 – Q3 2022 (4 quarters) LCDS Mobility Measure: Q4 2020 – Q3 2022 (8 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)

*The September 2020 refresh was postponed to December 2020 for technical reasons. The period of performance listed here reflects the data that was originally scheduled to be used to calculate provider performance for the December 2020 refresh.

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During 2020, we conducted testing to inform decisions about publicly reporting data for those refreshes which include partially and/or fully exempt data (discussed later in this section). The testing helped us develop a plan for posting data that are as up-to-date as possible and that also meet acceptable standards for public reporting. We believe that the plan allows us to provide consumers with helpful information on the quality of LTCH care, while also making the necessary adjustments to accommodate the exemption provided LTCHs. The following sections provide the results of our testing, and explains how we used

the results to develop plans for accommodating exempt and partially-exempt data in public reporting.

(2) Exempted Quarters

In the March 27, 2020 Medicare Learning Network (MLN) Newsletter on Exceptions and Extensions for Quality Reporting Program (QRP) Requirements, we stated that we would not report any PAC quality data that might be greatly impacted by the exemptions granted for Quarter 1 and Quarter 2 of 2020. Given the timing of the PHE onset, we determined that we would not use LCDS assessments or LTCH claims from Quarter 1 and Quarter 2 of 2020 for public reporting, but that we would assess the COVID–19 PHE impact on data from Quarter 4 2019. Before proceeding with the December 2020 refresh, we conducted testing to ensure that, despite the voluntary nature of reporting for that quarter, public reporting would still meet our public reporting standards. We found the level of reporting, measured in the number of eligible stays and providers, and the reported outcomes, to be in line with levels and trends observed in FY 2018 and FY 2019. We note that Quarter 4 2019 ended before the onset of the COVID–19 pandemic in the United States. Thus, we proceeded with including these data in LTCH QRP measure calculations for the December 2020 refresh.

(3) Update on Data Freeze for December 2021 Public Reporting Methodology for LTCH Claims-Based and LCDS Assessment-Based Measures

In addition to the March 2021 refresh, there are several other forthcoming refreshes for which the original public reporting schedules included exempted quarters of LTCH QRP data. The impacted refreshes for LCDS assessment and claims based measures are outlined in Table FF3. We determined that freezing the data displayed on the website with the December 2020 refresh values—that is, hold the data constant after the December 2020 refresh data on the website without subsequent update—would be the most straightforward, efficient, and equitable approach for LTCHs. Thus, we decided that, for as many refreshes as necessary, we would hold data constant on the website with the December 2020 data, and communicate this decision to the public.

Because December 2020 refresh data will become increasingly out-of-date and thus less useful for consumers, we analyzed whether it would be possible to use fewer quarters of data for one or more refreshes and thus reduce the number of refreshes that continue to display December 2020 data. Using fewer quarters of more up-to-date data requires that: (1) A sufficient percentage of LTCHs would still likely have enough assessment data to report quality measures (reportability); and (2) fewer quarters would likely produce similar measure scores for providers, with similar reliability, and thus not unfairly represent the quality of care LTCHs provide during the period reported in a given refresh (reliability).

To assess these criteria, we conducted reportability and reliability analysis using 3 quarters of data in a refresh, instead of the standard 4 quarters of data for reporting assessment-based measures and using 6 quarters instead of 8 for the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients requiring Ventilator Support (NQF #2632) measure; and using 6 quarters instead of 8 for claims-based measures. Specifically, we used historical data to calculate LCDS assessment based and LTCH claims based measures under two scenarios:

- *Standard Public Reporting (SPR) Base Scenario:* We used four quarters of CY 2019 data as a proxy alternative for the exempted quarters in CY 2020 in order to compare results. For assessment-based measures, the quarters used in this scenario are Q1 through Q4 2019. For the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients requiring Ventilator Support (NQF #2632) measure, the quarters used in this scenario are Q1 2018 through Q4 2019. For claims-based measures, the quarters used in this scenario are Q1 2018 through Q4 2019.
- *COVID–19 Affected Reporting (CAR) Scenario:* We calculated LTCH QRP measures using 3 quarters (Q2 2019 through Q4 2019) of LTCH QRP data for assessment-based measures, 6 quarters (Q1 2018 through Q4 2018 and Q3 2019 through Q4 2019) for the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients requiring Ventilator Support (NQF #2632) measure, and 6 quarters (Q1 2018 through Q4 2018 and Q3 2019 through Q4 2019) for claims-based measures. The CAR scenario uses the most recently available data to simulate the public health emergency reality where quarters 1 and 2 of a calendar year must be excluded from calculation. Quarterly trends in LCDS assessment-based and LTCH claims-based measures indicate that these measures do not exhibit substantial seasonal variation.

To assess performance in these scenarios, we calculated the reportability as the percent of LTCHs meeting the case minimum for public reporting (the public reporting threshold). To test the reliability of restricting the LTCHs included in the SPR Base Scenario to those included in the CAR Scenario, we performed three tests on the set of LTCHs included in both scenarios. First, we evaluated measure correlation using the Pearson and Spearman correlation coefficients, which assess the alignment of LTCHs' provider scores. Second, for each scenario, we conducted a split-half reliability analysis and estimated intraclass correlation (ICC) scores, where higher scores imply better internal reliability. Modest differences in ICC scores between scenarios would suggest that using fewer quarters of data does not impact the internal reliability of the results. Third, we estimated reliability scores where a higher value indicates that measure scores are relatively consistent for patients admitted to the same LTCH and variation in the measure reflects true differences across providers. To calculate the reliability results, we restricted the LTCHs included in the SPR scenario to those included in the CAR scenario. Our testing indicated that the expected impact of using fewer quarters of data on reportability and reliability of LCDS assessment-based and claims-based measures is acceptable.

We proposed to use the CAR scenario as the approach for the following affected refreshes: For LCDS assessment-based measures, the affected refresh is the December 2021 refresh; for claims-based measures, the affected refreshes occur from December 2021 through June 2023. For the earlier three affected refreshes (March, June and September 2021), we decided to hold constant the Care Compare website with December 2020 data. We communicated this decision in a Public Reporting Tip Sheet, which is located at: *https://www.cms.gov/files/document/LTCHqrp-covid19prtipsheet-october-2020.pdf*.

Our proposed CAR approach for the affected refreshes would allow us to begin displaying more recent data in December 2021, rather than continue displaying December 2020 data (Q1 2019 through Q4 2019 and Q1 2018 through Q4 2019 for assessment-based measures, Q4 2017 through Q3 2019 for claims-based measures). We believe resuming public reporting starting in December 2021 with fewer quarters of data can assist consumers by providing more recent quality data as well as more actionable data for LTCH providers. Our testing results indicate we can achieve these positive impacts with acceptable

changes in reportability and reliability. Table FF4 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for assessment-based measures. Table FF5 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for claims-based measures.

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TABLE FF4. REVISED AND FINAL SCHEDULE FOR REFRESHES AFFECTED BY COVID-19 PHE EXEMPTIONS FOR LCDS ASSESSMENT-BASED QMs

Quarter Refresh	LCDS Assessment based Quarters in Revised/ Final Schedule for Care Compare (number of quarters)^
December 2020	Q1 2019 – Q4 2019 (4) Q1 2018 – Q4 2019 (8)
March 2021	Q1 2019 – Q4 2019 (4) Q1 2018 – Q4 2019 (8)
June 2021	Q1 2019 – Q4 2019 (4) Q1 2018 – Q4 2019 (8)
September 2021	Q1 2019 – Q4 2019 (4) Q1 2018 – Q4 2019 (8)
December 2021	Q3 2020 – Q1 2021 (3) Q2 2019 – Q42019, Q3 2020 – Q1 2021 (6)
March 2022*	Q3 2020 – Q2 2021 (4) Q3 2019 – Q42019, Q3 2020 – Q2 2021 (6)
June 2022	Q4 2020 – Q3 2021 (4) Q42019, Q3 2020 – Q3 2021 (6)
September 2022	Q1 2021 – Q4 2021 (4) Q4 2019, Q3 2020 – Q4 2021 (7)
December 2022	Q2 2021 – Q1 2022 (4) Q4 2019, Q3 2020 – Q1 2022 (8)
March 2023**	Q3 2021 – Q2 2022 (4) Q3 2020 – Q2 2022 (8)

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

^The Change in Mobility Among LTCH Patients Requiring Ventilator Support requires 8 quarters of data whereas the remaining LCDS measures require 4 quarters.

*Normal reporting resumes with 4 quarters of data for most LCDS measures.

** All LCDS measures will normalize in the March 2023 refresh.

TABLE FF5. REVISED AND FINAL SCHEDULE FOR REFRESHES AFFECTED BY COVID-19 PHE EXEMPTIONS FOR LTCH CLAIMS-BASED QMs

Quarter Refresh	Claims-based Quarters in Revised/Final Schedule for Care Compare (number of quarters)
December 2020	Q4 2017 – Q3 2019 (8)
March 2021	Q4 2017 – Q3 2019 (8)
June 2021	Q4 2017 – Q3 2019 (8)
September 2021	Q4 2017 – Q3 2019 (8)
December 2021	Q4 2018 – Q4 2019, Q3 2020 (6)
March 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
June 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
September 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
December 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
March 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
June 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
September 2023	Q4 2020 – Q3 2022 (8)*

Note: The shaded cells represent data held constant due to PHE related to COVID-19.
*Normal reporting resumes with 8 quarters of data

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We invited public comments on the proposal to use the CAR scenario to publicly report LTCH measures for the December 2021–June 2023 refreshes. A summary of those comments and our responses follow.

Comment: Commenters generally did not support CMSs' proposal to utilize fewer than the standard number of quarters for public reporting of quality measures on Care Compare, stating that in many parts of the country, the highest rates of COVID–19 infections occurred after July 1, 2020 when LTCH QRP reporting requirements resumed, rather than in Q1 and Q2 of 2020 when LTCHs were exempted from LTCH QRP reporting requirements. They believe the Q3 2020 data collected were equally ''impacted,'' due to patients admitted with COVID–19 or recovering from COVID–19. They instead recommend that CMS should not resume the public display of new LTCH QRP data until the COVID–19 PHE is over.

Response: While we understand that there are concerns related to the use of Q3 and Q4 2020 data and beyond, we do not believe that further exempting providers from LTCH QRP reporting requirements, nor the continued suspension of public reporting, are actionable solutions. We granted a six-month exception to LTCH QRP reporting requirements due to the PHE under 42 CFR 412.560(c)(4)(i) of our regulations for Q1 and Q2 of 2020, a sufficient timeframe for LTCHs to adjust to the change in care patterns associated with the pandemic. We further believe that the public display of quality data is extremely important so patients and caregivers can continue to make informed healthcare choices. The continued need for access to LTCH QRP data on Care Compare by CMS beneficiaries outweighs potential LTCH impacts.

As described above, we conducted testing to inform our decisions about publicly reporting data for refreshes using Q3 and Q4 2020. As discussed in section IX.E.8.c.3. of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25621 through 25622), the testing helped us develop a plan that we believe meets acceptable standards for public reporting. LTCHs that believe they were disproportionately affected by the PHE may apply for an individual exception or extension to the LTCH QRP Q3 and/or Q4 2020 data submissions. Instructions for requesting an extraordinary circumstances exemption (ECE) may be found on the LTCH QRP Reconsideration and Exception and Extension web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Exception-and-Extension*.

Comment: A commenter requested that CMS include disclaimers on Care Compare to explain the potential impacts the PHE may have had on LTCH performance scores.

Response: We do not believe that posting additional messaging alluding to how LTCH measure scores may or may not be affected by the ongoing PHE would be helpful to consumers. Such messages would give the impression that the data posted on Care Compare are inaccurate or cannot be used when making informed healthcare decisions, which is not the case given the extensive testing CMS conducts.

Comment: A commenter stated that if CMS does decide to proceed with the public display of LTCH QRP data collected during the pandemic, they must notify LTCHs before the data is displayed.

Response: Historically, we have provided the following types of confidential provider feedback reports that give providers opportunity to review and correct data: (1) Review and Correct, which allows providers to review and correct their data for any given CY quarter, as early as one day following the end of the given quarter, but prior to the data submission deadline for that quarter, which falls approximately 4.5 months after the end of the quarter; and (2) Provider Preview Report, the purpose of which is to allow providers to preview their quality measure scores that will be publicly posted for the upcoming refresh of Care Compare, and also allows providers to

request a formal review of the data contained within, should the provider disagree with the reported measure results.

CMS also provides Quality Measure Reports (Facility and Patient-Level), the purpose of which is to allow providers to improve quality based on the most up-to-date data they have entered and/or modified within our systems. This report type is not related to public reporting, and is produced solely for the benefit of quality improvement. Quality measure Reports are not related to public reporting and do not observe the quarterly data submission deadlines of assessment-based data, and will continue to capture and include any and all data entered and/or modified beyond any data submission deadline. CMS provides Quality Measure Reports in order to give providers, including LTCHs, the most accurate picture of quality within their facility, allowing for the improvement of quality. While CMS has historically added new measures to the Quality Measure Reports prior to public reporting, the QM reports are not related to public reporting. Because we believe it is in the best interest of our beneficiaries that LTCHs publicly report the results of the COVID–19 Vaccination HCP measures as soon as it is feasible, in this instance, we are not able to add this measure to the QM reports prior to public reporting. Instead, we plan to add this new measure to the QM reports in fall 2022, at the earliest, but maintain that while this may be out of sequence compared to our actions historically, a delay will in no way affect a providers ability to review and/or correct their data for this measure, nor will it affect a LTCH's ability to preview the COVID–19 Vaccination HCP data prior to the public posting of this data.

The COVID–19 Vaccination HCP measure is stewarded by the CDC NHSN. To date, CMS has never added any of the CDC NHSN measures to the Review and Correct report, as the data for these measures are at the CDC. In lieu of this, the CDC makes accessible to PAC providers, including LTCHs, reports that are similar to the Review and Correct reports that allow for real-time review of data submissions for all CDC NHSN measures adopted for use in the CMS PAC QRPs, including the LTCH QRP. These reports are referred to as the ''CMS Reports'' within the Analysis Reports page in the NHSN Application. Such a report exists for each CDC/NHSN measure within the LTCH QRP, and each report is intended to mimic the data that will be sent to CMS on their behalf. This report will exist to serve the same ''review and correct'' purposes for the COVID–19 Vaccination HCP measure. The CDC publishes reference guides for each facility type (including LTCH) and each NHSN measure, which explain how to run and interpret the reports.

We will provide LTCHs with a preview of LTCH performance on the COVID–19 Vaccination HCP measure, as it will be available on the LTCH Provider Preview Report, which will be issued approximately 3 months prior to displaying the measure on Care Compare. As always, LTCHs will have a full 30 days to preview their data. Should a LTCH disagree with their measure results, they can request a formal review of their data by CMS. Instruction for submitting such a request are available on the LTCH QRP Reconsideration and Exception & Extension web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Exception-and-Extension*.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal as proposed to use the CAR scenario to publicly report LTCH measures for the December 2021–June 2023 refreshes.

(4) Update on Data Freeze for December 2021 Public Reporting Methodology for NHSN-Based Measures

CDC recommends using the four most recent non-contiguous non-exempted quarters of data for NHSN reporting in the LTCH QRP. This non-contiguous compilation of quarterly reporting would continue until the time when four contiguous quarters of reporting resumes (based on CDC's review, this would occur in July 2022). Tables FF6 and FF7 display the original schedules for public reporting of LTCH CDI, CAUTI and CLABSI measures and the HCP Influenza measure, respectively. Tables FF8 and FF9 summarize the revised schedule and finalized schedule for LTCH CDI, CAUTI, and CLABSI measures and the HCP Influenza measure, respectively.

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TABLE FF6. LTCH QRP QUARTERS IN CARE COMPARE ORIGINAL SCHEDULE FOR REFRESHES AFFECTED BY COVID-19 PHE EXEMPTIONS CDI, CAUTI, AND CLABSI NHSN MEASURES

Quarter Refresh	CDI, CAUTI, and CLABSI Quarters in Original Schedule for Care Compare (number of quarters)
Actual December 2020 (on Care Compare)	Q4 2018 – Q3 2019 (4)*
Original December 2020	Q1 2019 – Q4 2019 (4)
March 2021	Q2 2019 – Q1 2020 (4)
June 2021	Q3 2019 – Q2 2020 (4)
September 2021	Q4 2019 – Q3 2020 (4)
December 2021	Q1 2020 – Q4 2020 (4)
March 2022	Q2 2020 – Q1 2021 (4)
June 2022	Q3 2020 – Q2 2021 (4)

*The September 2020 refresh was postponed to December 2020 for technical reasons.

TABLE FF7. LTCH QRP QUARTERS IN CARE COMPARE ORIGINAL SCHEDULE FOR REFRESHES AFFECTED BY COVID-19 PHE EXEMPTIONS - HCP INFLUENZA MEASURE

Quarter Refresh	HCP Influenza Quarters in Original Schedule for Care Compare (number of quarters)
Actual December 2020 (on Care Compare)	Q4 2017 – Q1 2018 (2)*
December 2020	Q4 2018 – Q1 2019 (2)
March 2021	Q4 2018 – Q1 2019 (2)
June 2021	Q4 2018 – Q1 2019 (2)
September 2021	Q4 2018 – Q1 2019 (2)
December 2021	Q4 2019 – Q1 2020 (2)
March 2022	Q4 2019 – Q1 2020 (2)
June 2022	Q4 2019 – Q1 2020 (2)
September 2022	Q4 2019 – Q1 2020 (2)
December 2022	Q4 2020 – Q1 2021 (2)

*The September 2020 refresh was postponed to December 2020 for technical reasons.

TABLE FF8. REVISED AND FINAL SCHEDULE FOR REFRESHES AFFECTED BY COVID-19 PHE EXEMPTIONS FOR THE CDI, CAUTI, AND CLABSI NHSN MEASURES

Quarter Refresh	CDI, CAUTI, and CLABSI Quarters in Revised/Final Schedule for Care Compare (number of quarters)
December 2020	Q4 2018 – Q3 2019 (4)
March 2021	Q4 2018 – Q3 2019 (4)
June 2021	Q4 2018 – Q3 2019 (4)
September 2021	Q4 2018 – Q3 2019 (4)
December 2021	Q1 2019 – Q4 2019 (4)
March 2022	Q2 2019 – Q4 2019, Q3 2020 (4)
June 2022*	Q3 2020 – Q2 2021

Note: The shaded cells represent data held constant due to PHE related to COVID-19.
* Normal reporting resumes with 4 contiguous quarters of data.

TABLE FF9. REVISEDAND FINAL SCHEDULE FOR REFRESHES AFFECTED BY COVID-19 PHE EXEMPTIONS FOR THE HCP INFLUENZA NHSN MEASURE

Quarter Refresh	HCP Influenza Quarters in Revised Schedule for Care Compare (number of quarters)
December 2020	Q4 2017 – Q1 2018 (2)
March 2021	Q4 2017 – Q1 2018 (2)
June 2021	Q4 2017 – Q1 2018 (2)
September 2021	Q4 2017 – Q1 2018 (2)
December 2021	Q4 2018 – Q1 2019 (2)
March 2022	Q4 2018 – Q1 2019 (2)
June 2022	Q4 2018 – Q1 2019 (2)
September 2022	Q4 2018 – Q1 2019 (2)
December 2022	Q4 2020 – Q1 2021 (2)*

Note: The shaded cells represent data held constant due to PHE related to COVID-19.
* Normal reporting resumes.

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F. Changes to the Medicare Promoting Interoperability Program

1. Background

a. Statutory Authority for the Medicare Promoting Interoperability Program

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorized incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare were available to eligible hospitals and critical access hospitals (CAHs) for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrated meaningful use of certified electronic health record technology (CEHRT), which included reporting on clinical quality measures using CEHRT. Incentive payments were available to Medicare Advantage (MA) organizations under section 1853(m)(3) of the Act for certain affiliated hospitals that successfully demonstrated meaningful use of CEHRT. In accordance with the timeframe set forth in the statute, these incentive payments under Medicare generally are no longer available, except for Puerto Rico eligible hospitals. For more information on the Medicare incentive payments available to Puerto Rico eligible hospitals, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58976 and 58977) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41672 through 41675).

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act also established downward payment adjustments under Medicare, beginning with fiscal year (FY) 2015, for eligible hospitals and CAHs that did not successfully demonstrate meaningful use of CEHRT for certain associated electronic health record (EHR) reporting periods. Section 1853(m)(4) of the Act established a negative payment adjustment to the monthly prospective payments for a qualifying MA organization if its affiliated eligible hospitals are not meaningful users of CEHRT, beginning in 2015.

Section 1903(a)(3)(F)(i) of the Act established 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade, and meaningfully use CEHRT. We previously established, however, that in accordance with section 1903(t)(5)(D) of the Act, in no case may any Medicaid eligible hospital receive an incentive after calendar year (CY) 2021 (42 CFR 495.310(f), 75 FR 44319). Therefore, December 31, 2021 is the last date that States could make Medicaid Promoting Interoperability Program payments to Medicaid eligible hospitals (other than pursuant to a successful appeal related to CY 2021 or a prior year) (84 FR 42591 through 42592). For additional discussion or context around the discontinuation of the Medicaid Promoting Interoperability Program, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41676 through 41677).

2. EHR Reporting Period

a. Background

Under the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4, the EHR reporting period in CY 2022 is a minimum of any continuous 90-day period in CY 2022 for new and returning participants in the Medicare Promoting Interoperability Program. Eligible hospitals and CAHs may select an EHR reporting period of a minimum of any continuous 90-day period in CY 2022 (from January 1, 2022 through December 31, 2022) (85 FR 58966 through 58967). Since the EHR reporting period in CY 2015 (see 80 FR 62777 through 62781, and the definitions of EHR reporting period and EHR reporting period for a payment adjustment year at 495.4), we have consistently established an EHR reporting period of a minimum of any continuous 90-day period for eligible hospitals and CAHs for the Medicare Promoting Interoperability Program in order to provide maximum flexibility to providers and their health IT vendors.

b. EHR Reporting Period in CY 2023 and CY 2024 for Eligible Hospitals and CAHs

For CY 2023, in the FY 2022 IPPS/LTCH proposed rule (86 FR 25628 through 25629), we proposed to continue the EHR reporting period of a minimum of any continuous 90-day period for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program.

For CY 2024, in the FY 2022 IPPS/LTCH proposed rule (86 FR 25628 through 25629), we proposed an EHR reporting period of a minimum of any continuous 180-day period for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program.

We also proposed to amend the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4, to include these proposed EHR reporting periods in CYs 2023 and 2024.

The CY 2024 proposal would minimally increase the information collection burden on data submitters, and having additional data available to further improve our program is beneficial. In increasing the EHR reporting period in CY 2024, this would allow eligible hospitals, CAHs, and vendors time to plan in advance, build upon, and utilize investments already made within their infrastructure. Reporting on additional data would also provide eligible hospitals and CAHs the opportunity to continuously monitor their performance and identify areas that may require investigation and corrective action. Increasing the EHR reporting period in CY 2024 is important for the continued improvement of interoperability and health information exchange by producing more comprehensive and reliable data for patients and providers, which are key goals of the Medicare Promoting Interoperability Program.

We sought comments on the proposed EHR reporting periods in CYs 2023 and 2024, and proposed changes to the regulation text at 42 CFR 495.4.

Comment: Many commenters supported the EHR reporting period proposal to maintain the current policy of a minimum of any continuous 90-day period for CY 2023. Commenters emphasized that this consistency will allow eligible hospitals and CAHs ample time to implement the 2015 Edition Cures Update and to complete required testing allowing continued flexibility for planned system downtimes, and routine system upgrade cycles.

Response: We thank commenters for their support of the CY 2023 EHR reporting period proposal. We agree that for CY 2023, keeping the EHR reporting period at a minimum of any continuous 90-days will afford eligible hospitals and CAHs the individual site-specific flexibility they might need while implementing the 2015 Edition Cures Update and preparing for a lengthening of the EHR reporting period of a minimum of any continuous 180-days for CY 2024.

Comment: Some commenters were supportive of the proposed increase to the EHR reporting period to a minimum of any continuous 180-days in CY 2024, but shared concerns related to the 2015 Edition Cures Update implementation deadlines. Specifically, commenters expressed concerns that the 2015 Edition Cures Update may require extended testing periods until the updates have been fully implemented. Commenters are concerned that extended testing will result in scheduled and unscheduled downtime, limiting their ability to report on a minimum of a continuous, but unaffected, 180-day period. A few commenters also had concerns surrounding routine system upgrades and scheduled downtimes limiting their ability to report on a minimum of a continuous 180-day period.

Response: We thank commenters for supporting the lengthening of the EHR reporting period and sharing their implementation concerns. We believe that an EHR reporting period for CY 2024 of 180 days will not impact eligible hospitals and CAHs efforts to update, implement, and test their EHR systems to maintain compliance with the 2015 Edition Cures Update. Eligible hospitals and CAHs must use certified EHR technology updated to the 2015 Edition Cures Update during an EHR reporting period in 2023 of their choosing; therefore, they should have completed implementation by 2024 (86 FR 25628 through 25629). We also believe that by proposing and finalizing this increase in the FY 2022 IPPS/LTCH PPS proposed and final rules, eligible hospitals and CAHs will have more than two years of planning with their respective vendor to meet site-specific needs for implementation and future planning for a longer EHR reporting period. For information on the timelines associated with the 2015 Edition Cures Update and associated final policies for the Medicare Promoting Interoperability Program, we refer commenters to the Office of the National Coordinator for Health Information Technology's (ONC) 21st Century Cures Act final rule (85 FR 25642 through 25961), and the CY 2021 PFS final rule (85 FR 84815 through 84825). For commenters concerned with limited flexibility in choosing a 180-day reporting period when considering general updates to health IT systems or transitions between health IT systems, we suggest early planning with vendors on the timing of routine system updates and downtimes to allow for maximum flexibility in choosing their 180-day reporting period.

Comment: Some commenters supported our proposal to increase the length of the EHR reporting period, but have asked that we delay implementation until CY 2025. Commenters expressed that the additional year will ensure that eligible hospitals and CAHs have had enough time to recover from the COVID–19 PHE.

Response: We thank commenters for their feedback. We understand the continued efforts required of eligible hospitals and CAHs throughout the COVID–19 PHE. We believe that the COVID–19 PHE has highlighted areas where we can focus our efforts to include allowing eligible hospitals and CAHs the opportunity to monitor their performance over a longer EHR reporting period, and to identify areas that may require investigation and corrective action. This is important for the continued improvement of interoperability and health information exchange, which are key goals of the Medicare Promoting Interoperability Program.

Comment: A few commenters supported lengthening the EHR reporting period, but suggest permanently adopting an exception which allows for a 90-day EHR reporting period for eligible hospitals and CAHs that undergo EHR vendor transitions or system upgrades in any given year.

Response: We would like to thank these commenters for their suggestions, and will take this feedback under consideration for future program years. We would like to note that through CY 2023, the 90-day EHR reporting period has been finalized as a minimum requirement, and that eligible hospitals and CAHs are continuously encouraged to use longer reporting periods, up to and including the full calendar year. Additionally, we would like to remind commenters that the Medicare Promoting Interoperability Program allows hardship exception applications for extreme and uncontrollable circumstances, including vendor issues. Additional information on this process is available at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj_Hardship*.

Comment: Several commenters did not support the proposed lengthening the EHR reporting period in CY 2024, and instead suggest maintaining the policy at 90-days for CY 2023 and all subsequent years. Commenters were concerned that the additional reporting requirements lend themselves to increased reporting burden, and could contribute to clinical burnout due to non-clinical work.

Response: We would like to thank commenters for their suggestions. The EHR reporting period was first established in the Stage 1 final rule (75 FR 44320) as a minimum of any continuous 90-day period beginning with the first payment year, and each successive year. We disagree that in lengthening the EHR reporting period from 90-days to 180-days will cause clinicians additional burden due to non-clinical requirements, and would like to reiterate that we have maintained the 90-day reporting period policy since 2011. With electronic reporting, there is no additional requirement or action needed by clinical staff to account for the longer EHR reporting period. As continue to strive towards promoting greater use of interoperable health IT, balanced against systemic requirements and limitations, and will continue to take commenters' feedback and concerns under consideration with our policies.

After consideration of the public comments we received, we are finalizing our proposal that for CY 2023, the EHR reporting period is a minimum of any continuous 90-day period in CY 2023 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program. We are finalizing our proposal that for CY 2024 the EHR reporting period is a minimum of any continuous 180-day period in CY 2024 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program. We are also finalizing the corresponding changes to the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4 as proposed.

3. Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

a. Measure Background

We have adopted a Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing objective. For background on this measure, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41648 through 41656), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42596), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969). In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969), we finalized that the Query of PDMP measure will remain optional and eligible for 5 bonus points in CY 2021.

b. State PDMPs' Progress and Previous Stakeholder Feedback

In the FY 2020 and FY 2021 IPPS/LTCH PPS final rules (84 FR 42593 through 42596 and 85 FR 58967 through 58969), we described the concern expressed by stakeholders that they believed it was premature for the Medicare Promoting Interoperability Program to require the Query of PDMP measure and score it based on performance. Feedback received from health IT vendors and hospitals expressed that flexibility in the measure presents unintended challenges such as significant burden associated with IT system design and additional development needed to accommodate the measure and any future changes to it.

We understand that there is wide variation across the country in how health care providers are implementing and integrating PDMP queries into health IT and clinical workflows, and that it could be burdensome for health care providers if we were to narrow the measure to specify a single approach to PDMP–EHR integration at this time. At the same time, we have heard extensive feedback from EHR developers that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust measurement specifications. These stakeholders stated that health IT developers may face significant cost burdens if they fully develop numerator and denominator calculations for all the potential use cases and are required to change the specification at a later date. Stakeholders have stated that the costs of additional development will likely be passed on to health care providers without additional benefit as this development would be solely for the purpose of calculating the measure rather than furthering the clinical goal of the measure (for public comments discussed in last year's final rule, we refer readers to 85 FR 58967 through 58969).

In support of efforts to expand the use of PDMPs, there are currently a number of federally supported activities underway aimed at developing a more robust and standardized approach to EHR–PDMP integration. Federal partners, including the Centers for Disease Control and Prevention (CDC) and the Office of the National Coordinator for Health Information Technology (ONC), and private sector stakeholders, are focused on developing and refining standard-based approaches to enable effective integration into clinical workflows, exploring emerging technical solutions to enhance access and use of PDMP data, and providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs. Moreover, a number of enhancements to PDMPs are occurring across the country, including enhancements to RxCheck, which is a federally supported interstate exchange hub for PDMP data.[1357] The ONC Interoperability Standards Advisory describes current and emerging standards related to PDMP and opioid use disorder (OUD) data capture and exchange that would allow a provider to request a patient's medication history from a State PMDP and for PDMP data to be exchanged between systems and states.[1358] We believe these standards and technical approaches are likely to rapidly reach maturity to support exchange across health care system stakeholders.

The SUPPORT for Patients and Communities Act (Pub. L. 115–271), enacted in 2018, is an important investment in combating the opioid epidemic. Several of the provisions of the SUPPORT for Patients and Communities Act address opioid use disorder prevention, recovery, and treatment, including legislative changes specific to the Medicare and Medicaid programs intended to increase access to evidence-based treatment and follow-up care. However, with respect to PDMPs, the SUPPORT for Patients and Communities Act included new requirements and Federal funding for PDMP enhancement, integration, and interoperability, and established mandatory use of PDMPs by certain Medicaid providers to help reduce opioid misuse and overprescribing and to help promote the overall effective prevention and treatment of opioid use disorder beginning in October of 2021.

c. Measure Changes

Given current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), our ongoing review of alternative measure approaches, and stakeholder concerns about the current readiness across states for implementation of the existing measure, we believe that at least one more year is needed prior to potentially requiring the Query of PDMP measure.

[1357] *https://www.pdmpassist.org/RxCheck.*

[1358] *https://www.healthit.gov/isa/allows-a-provider-request-a-patients-medication-history-a-state-prescription-drug-monitoring.*

While we appreciate the concerns that stakeholders have shared, we continue to believe that this measure can play an important role in helping to address the opioid crisis. By integrating PDMP data into the health record, health care providers can improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions. Maintaining it as an optional measure with bonus points signals to the hospital and vendor community that this is an important measure which addresses a current gap that can help spur development and innovation in order to reduce barriers and challenges.

Therefore, in the FY 2022 IPPS/LTCH proposed rule (86 FR 25629 through 25630), we proposed for the EHR reporting period in CY 2022 to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing its associated bonus points from 5 points to 10 points, as well as proposed corresponding changes to the regulation at § 495.24(e)(5)(iii)(B). As a result of this proposal, the maximum total points available for the Electronic Prescribing Objective would increase to 20 points for CY 2022, and we proposed to revise § 495.24(e)(5)(ii)(B) to reflect this increase. This proposed increase of the measure's associated bonus points to 10 points is consistent with the policy finalized for MIPS eligible clinicians in the CY 2021 PFS final rule (85 FR 84887 through 84888) and would be in alignment with the MIPS Promoting Interoperability performance category.

d. Health IT Updates and Measure Direction

Given recent progress in a variety of areas, we believe that there is now a clearer trajectory forward to potentially requiring the Query of PDMP measure. These developments include updated requirements for certified health IT, standards development activities around PDMPs, and other projects that can more tangibly inform future policy changes. For example, under final policies recently adopted in the CY 2021 Physician Fee Schedule final rule (85 FR 84815 through 84828), participants in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category will begin using certified EHR technology incorporating application programming interfaces (APIs) based on HL7® FHIR® standard version Release 4 in CY 2023 consistent with updates to certified health IT which were finalized in the ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (hereinafter referred to as the ''ONC 21st Century Cures Act final rule''), published in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961 and 25740).[1359] Updates to 2015 Edition health IT certification criteria in the ONC 21st Century Cures Act final rule also incorporated NCPDP SCRIPT standard version 2017071 for electronic prescribing. The availability of both standardized APIs and updated standards for e-prescribing within certified health IT could serve as a stepping stone to future technical approaches that enable more seamless exchange of data between CEHRT and PDMP systems.

ONC also began work in partnership with the CDC, the Department of Justice's Bureau of Justice Assistance, and the eHealth Exchange to develop a prototype to pilot an innovative technical solution for the delivery of patient medication histories across State lines via HL7® FHIR®. The eHealth Exchange is a network of networks that is active in all 50 states connecting Federal and non-Federal healthcare organizations to improve patient care and public health. To date, the prototype has been successfully tested in several states. Early prototype testing used synthetic data to evaluate system capacity to send and receive a patient's medication history request and response. The goal of the project is to allow any provider who is live on the eHealth Exchange to use that existing connection to query a patient's record on the RxCheck Hub, which routes the query to individual State PDMPs who are also live on RxCheck. This solution will enable providers to query PDMPs via existing connections to health information exchange networks as a way to: (1) Leverage existing technology, (2) reduce burden associated with multiple, disparate system interfaces and workflows, and (3) allow for the exchange and full integration of data within allowable law from the point of exchange for medication reconciliation, allergy checks, and other forms of clinical decision support.

Based upon these developments, which are advancing enhanced certified functionality, effective functional data exchange, and the use of open, mature standards, we believe there is a much better informed roadmap for achieving better integration between PDMPs and EHRs with enhanced interoperability of controlled prescription data across states and systems. We believe that as these activities develop, they can help to address some of the previous concerns raised by stakeholders around this measure, and we will continue to work with ONC to monitor these activities.

We sought comments on our proposal to maintain the Query of PDMP measure in the EHR reporting period in CY 2022 as optional and to increase the bonus points associated with the measure to 10 bonus points.

Comment: The vast majority of commenters agreed with the proposal to maintain the Electronic Prescribing Objective's Query of PDMP measure in the CY 2022 EHR reporting period as optional and to increase the bonus points associated with the measure to 10 bonus points. Many of the commenters who supported the proposal referenced how the implementation methods under each state still vary greatly due to the uniqueness of local laws for each particular PDMP's jurisdiction. The same commenters also appreciated that the increase in available bonus points to 10 points is consistent with a similar policy finalized by the Merit-based Incentive Payment System (MIPS) eligible clinicians in the CY 2021 PFS final rule, therefore maintaining an aspect of alignment with the MIPS Promoting Interoperability performance category.

Response: We thank commenters for their support for the proposal as we recognize that additional time before requiring the Query of PDMP measure would enable further progress to be made around integration between PDMPs and EHR systems. We acknowledge that there is some complexity for how various state programs are maturing their systems toward the development of effective PDMP–EHR integration and we continue to collaborate with our various partners (including but not limited to the Office of the National Coordinator for Health Information Technology, ONC) to increase access and promote further use of standards to support exchange of information with PDMPs. This ongoing partnership to develop more consistent and interoperable approaches to sharing data with PDMPs will inform continued progress in this area of health information exchange, while our proposal would provide for an additional year for states and other stakeholders to make greater progress toward improving interoperability across systems.

Comment: Some commenters who supported the proposal also suggested that CMS should continue to maintain the Query of PDMP measure as optional beyond CY 2022 in order to help lift undue burden off the facilities which

[1359] HL7® and FHIR® are registered trademarks of Health Level Seven International.

are still struggling to seamlessly integrate EHR systems with PDMPs. Similarly, some commenters supported the intent of the measure and support the role it plays in improving patient care by potentially protecting vulnerable populations from opioid overdoses, but suggested that the measure should not be required until PDMPs are able to give providers a full, real-time accounting of patients' prescription drug history.

Response: We thank commenters for expressing their concerns regarding requiring the Query of PDMP measure in the future. However, we continue to believe the Query of PDMP measure will be a useful and informative measure as more state PDMPs and hospital EHR systems are effectively integrated. We refer readers to section IX.F. of the proposed rule and this final rule for an overview of the key efforts which have been underway and highlighted aims of improving the technical approaches to EHR–PDMP integration, including the implementation of key provisions from the SUPPORT for Patients and Communities Act. The proposal was only for the CY 2022 EHR reporting period. We will take commenters' feedback into consideration in proposals for future years of the program.

After consideration of the public comments received, we are finalizing our proposal to maintain the Query of PDMP measure as optional while increasing its associated bonus points from 5 points to 10 points for the EHR reporting period in CY 2022. As a result, the maximum total points available for the Electronic Prescribing Objective will increase to 20 points for the EHR reporting period in CY 2022. We are also finalizing the corresponding changes to the regulation at §§ 495.24(e)(5)(ii)(B) and 495.24(e)(5)(iii)(B) as proposed.

4. Changes to the Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

a. Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41668), we renamed the Patient Electronic Access Objective to the Provider to Patient Exchange Objective. This objective includes the Provide Patients Electronic Access to Their Health Information measure.

b. Data Availability Requirement for Eligible Hospitals and CAHs

In the FY 2022 IPPS/LTCH proposed rule (86 FR 25631), we proposed to modify the Provide Patients Electronic Access to Their Health Information measure by requiring eligible hospitals and CAHs to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely, using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT, as described under 495.24(e)(7)(ii)(B). Eligible hospitals and CAHs would be required to ensure this information remain available indefinitely (that is, not merely for a defined period of time). As proposed, this requirement would apply beginning with the EHR reporting period in CY 2022, and would include all patient health information from encounters on or after January 1, 2016. We also proposed to add corresponding regulatory text at 495.24(e)(7)(ii)(C), as well as restructuring some of the existing text under 495.24(e)(7) to improve clarity and readability.

In the Patient Access and Interoperability final rule (85 FR 25510, 25527 through 25528), we finalized that beginning on January 1, 2021, MA organizations, Medicaid FFS programs, Medicaid managed care plans, CHIP FFS programs, CHIP managed care entities, and QHP issuers on the FFEs must make available to beneficiaries and enrollees through a Patient Access API, certain claims and clinical data that they maintain with a date of service on or after January 1, 2016. Recognizing the challenges faced by payers during the COVID–19, we announced we will exercise enforcement discretion and not enforce these new requirements until July 1, 2021.[1360] The look-back period finalized in the Patient Access and Interoperability final rule aimed to align with the required policy for payer-to-payer data exchange finalized in the same rule, providing patients with the same timeframe of information as payers to ensure consistent implementation, while minimizing cost and burden and maximizing patient benefit (85 FR 25542). The finalized look-back period for payers also required that data be available for 5 years after disenrollment (§ 422.119(f)).

Currently, the Provide Patients Electronic Access to Their Health Information measure does not specify how long eligible hospitals and CAHs are required to make patient data available or ensure that patient data remain available to patients in the event that an eligible hospital or CAH switches EHR vendors. In an effort to minimize stakeholder burden, we wanted to align the date under our proposal for making information about encounters available, with the date of service start date (January 1, 2016) as finalized in the Patient Access and Interoperability final rule. As an alternative to our proposal, we considered different encounter start dates, such as encounters on or after January 1, 2012, or encounters on or after January 1, 2019. We believe, however, that a requirement for hospitals to ensure patient health information remains available indefinitely, as well as an encounter start date of January 1, 2016 would provide the most benefit to patients when accessing their health information as compared to the burden and costs to eligible hospitals and CAHs implementing these proposed requirements.

We sought public comments on our proposals to modify the Provide Patients Electronic Access to Their Health Information measure, as well as the alternatives we considered and discussed above.

Comment: A commenter expressed support for our proposal, stating that aligning requirements across the healthcare sector would minimize confusion and burden for hospitals.

Response: We would like to thank this commenter for their support, and agree that as we continue to align requirements across program areas, this will minimize reporting burden and redundancies.

Comment: Many commenters support the principle that patients should have prompt access to their data with minimal effort, but did not support our proposal as proposed. Several commenters stated that the lack of clarity around key terminology was a main concern. Specifically, commenters requested additional clarification on how we are defining an ''indefinite'' timeline, what specific data would be included in ''all patient health information,'' and how we will address software platform changes regarding non-transferable data given those terms.

Response: We thank commenters for their feedback, and agree that patients should have access to their data with minimal effort. For commenters requesting additional clarification on the terms used in the proposal, including ''indefinite'' and ''all patient health information,'' thank you for these requests. We agree with commenters that we need to more clearly define what an ''indefinite'' timeline entails, as well as to more clearly define what specific data should be included in ''all patient health information.'' We agree with commenters that we need to consider defining and allowing for

[1360] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index.*

exceptions as well. We agree that as proposed, this modification needs additional clarification, and for these reasons, we are not finalizing this proposal at this time. In the future, we will be seeking additional feedback from eligible hospitals and CAHs, in the event that we decide to propose changes to the measure in future rulemaking.

Regarding software platform changes and non-transferable data, we would like to note that the ONC 21st Century Cures Act final rule established a new criterion, ''electronic health information export'' at § 170.315(b)(10), which requires a certified health IT module to electronically export all electronic health information (EHI), as defined in § 171.102, that can be stored at the time of certification by the product of which the health IT module is a part (85 FR 25690–25693). A health IT developer of certified health IT products, which, at the time presented for certification electronically stores EHI, must certify such products to this new criterion and make these products available to their customers by December 31, 2023. We believe this certified functionality will further support the capability to seamlessly transfer electronic health information between systems. Although we are not finalizing this proposal at this time, we will consider these suggestions in the event we decide to propose changes to the measure in future rulemaking.

Comment: Several commenters shared concerns regarding potential conflict between state laws and our proposed data availability requirement, and also between state laws and our proposed requirement to make available ''all patient health information.'' One example shared by a few commenters is that different states have different timeline requirements for data retention (mentioned were 7 and 10 years), as opposed to our proposal for an ''indefinite'' availability period. Another commenter shared that some states have laws requiring that physicians withhold certain patient health information from being released (specifically, California protected health information laws were shared), where our proposal included ''all patient health information,'' non-specific of any exclusions.

Response: We thank commenters for sharing this feedback and their concerns. We agree with commenters that we need to continue our collaborative efforts with the CMSPatient Access and Interoperability team and ONC as we consider how we might address this issue in future rulemaking. We also agree with commenters that we need to address varying data availability requirements between individual states, and ensure that we also account for state protected personal health information. For these reasons, we are not finalizing our proposal at this time. Instead, CMS may hold a listening session in the future where we welcome feedback as we continue to consider potential revisions to this measure amidst the feedback we have received.

Comment: Many commenters were not supportive of our proposal, but offered suggestions for us to consider. A few commenters suggested that CMS consider setting expectations on a forward-looking basis rather than taking a retrospective approach. Some commenters suggested that we consider working more closely with ONC to clearly distinguish between USCDI and the larger set of electronic health information as defined in the ONC Information Blocking rules. Another commenter asked that we ensure this policy is aligned with ONC's requirements for certified health IT. A commenter suggested that we consider postponing this policy until the Patient Access and Interoperability final rule has been fully implemented before expanding into the Medicare Promoting Interoperability Program. A commenter suggested that we consider requiring hospitals to support any API of the patient's choosing, then follow with the data retention requirement over time.

Response: Again, we thank commenters for sharing their suggestions for improvement. We agree with the commenters' suggestions, and will continue to collaborate with the CMS Patient Access and Interoperability team and ONC, especially regarding the feedback commenters shared above. We agree with commenters that CMS and ONC need to clearly distinguish between the USCDI requirements against the larger set of electronic health information, especially in light of this proposed modification. We agree with commenters that additional work is essential on this proposal, and will not be finalizing at this time. We will take into consideration the suggestion to consider postponing this policy until the Patient Access and Interoperability final rule has been fully implemented, and as mentioned previously, CMS may hold a listening session in the future where we welcome additional feedback as we consider this measure for future rulemaking.

After consideration of the public comments we received, we are not finalizing our proposal to modify the Provide Patients Electronic Access to Their Health Information measure by requiring eligible hospitals and CAHs to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT, as described under 495.24(e)(7)(ii)(B). We are also not finalizing our proposals to add and restructure corresponding regulatory text at § 495.24(e)(7)(ii)(C) and § 495.24(e)(7). We wish to emphasize that CMS and HHS strongly believe that a patient's health information remain available to the patient (or patient-authorized representative) through available technology tools, including the technology capabilities specified to successfully report on the Provide Patient Access to the Health Information measure. We will take commenters' suggestions under consideration and will seek further input as we consider whether to propose changes to the measure in future rulemaking.

5. Health Information Exchange Objective: Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)

a. Background

Organizations that provide health information exchange services (HIEs) allow for the sharing of health information among clinicians, hospitals, care coordinators, labs, radiology centers, and other health care providers through secure, electronic means so that health care providers can have the benefit of the most recent information available from other health care providers. HIEs allow for broader interoperability beyond one health system or point-to-point connections among payers, patients, and health care providers. By enabling bi-directional exchange of information between health care providers and aggregating data across providers with disparate systems, HIEs can bring together the information needed to create a true longitudinal care record and support improved care coordination by facilitating timely access to robust health information across care settings. In the FY 2022 IPPS/LTCH proposed rule (86 FR 25631 through 25634), we stated that for the purposes of this proposal, bi-directional exchange means that the hospital's EHR enables querying and sharing data by sending, receiving, and incorporating data via an HIE for all unique patients treated in place of service inpatient hospital or emergency department (POS 21 and 23 respectively). Healthcare quality and public health outcomes have been shown in multiple studies to experience a beneficial effect from

health information exchanges with improved medication reconciliation, improved immunization and health record completeness, and improved population level immunization rates,[1361] while other research has shown a decrease in emergency department utilization and improved care process when using an HIE.[1362]

HIE services are available from many organizations today, which may be referred to as HIEs, health information networks, health information organizations (HIOs), or other terms. State and regional HIEs have a long history of connecting health care providers caring for a common patient population across a specified geographic area. These HIEs represent a significant public investment, with $564 million in Federal funding provided as part of the 2009 HITECH Act, ongoing State funding and support from CMS under both 42 CFR 495.322 and 42 CFR 433 Subpart C.[1363] These State and regional HIEs typically obtain not just EHR-generated data, but a broader array of ADT (admit, discharge, transfer) feeds and lab feeds as they build on local relationships. These HIEs may have similar but not identical capabilities, employing different models of data storage and a variety of business models. Regional and State-based exchanges have also begun to address national-level exchange, with efforts designed to link State and regional networks so that health care providers can obtain information on individual patients wherever they receive care throughout the United States. In addition to these initiatives, many EHR vendors are participating in the development of national-level networks designed to ensure their customers can share information with customers of other vendors. For data on HIE availability and adoption, we refer readers to 86 FR 25632.

b. New Health Information Exchange (HIE) Bi-Directional Exchange Measure

We believe that incentivizing participation in HIEs that support bi-directional exchange will contribute to a longitudinal care record for the patient and facilitate enhanced care coordination across settings. The use of an HIE means that essential health information is available for care team members even in the case of referrals the clinician may not be aware of, or for instances where the eligible hospital or CAH is contributing to the patient's record, but may not be the health care provider making the referral. In these instances, such transitions may or may not be able to be automatically identified by an EHR for inclusion in the denominators of the two existing measures associated with the HIE objective for the Promoting Interoperability Program (42 CFR 495.24(e)(6)).

Under the existing measures for the HIE objective (42 CFR 495.24(e)(6)), only the known transition of care from primary care physician to specialist would be included in the denominator. However, under the alternative measure for bi-directional exchange through a HIE that we proposed, we would incentivize the eligible hospital or CAH to engage in health information exchange for care coordination that includes these additional transitions and referrals as well as other potential scenarios: Where the recipient of the transition of care may be unknown; where the eligible hospital or CAH may not be the referring health care provider; where the transition of care may happen outside the scope of the EHR reporting period. In this way, the eligible hospital or CAH's action to engage in bi-directional exchange through an HIE would allow each health care provider to contribute to the longitudinal care record in a manner that supports a wide range of transitions and referrals beyond those currently reflected in the measure denominators. This engagement supports robust health information exchange without placing burden on the hospital or the patient to be individually accountable to facilitate exchange via multiple (and potentially unknown) point-to-point connections.

The COVID–19 public health emergency (PHE) has further highlighted the need to encourage interoperable HIE infrastructure and bi-directional exchange across the country that can ensure patients, health care providers, and public health authorities have the data they need to support quality care. In addition to supporting general care coordination, HIEs can specifically support the PHE response by facilitating enhanced use of telehealth and telemedicine through obtaining and aggregating patient information including when the patient's health care provider(s) may not be known.

In the CY 2021 PFS final rule (85 FR 84888 through 84893), we added an alternative measure for bi-directional exchange through a HIE under the Health Information Exchange objective for the MIPS Promoting Interoperability performance category beginning with the performance period in 2021. In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to add a similar measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022 (86 FR 25631–25634).

We proposed at 86 FR 25631 through 25634 to add the following new measure for inclusion in the Health Information Exchange objective at 42 CFR 495.24(e)(6)(ii)(C): Health Information Exchange (HIE) Bi-Directional Exchange measure. We proposed to add this new HIE Bi-Directional Exchange measure to the HIE objective as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure 42 CFR 495.24(e)(6)(ii)(A) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure 42 CFR 495.24(e)(6)(ii)(B). We proposed that eligible hospitals and CAHs may either report the two existing measures and associated exclusions OR may choose to report the new measure and are proposing to revise 42 CFR 495.24(e)(6)(ii) to reflect this change. We proposed that the HIE Bi-Directional Exchange measure would be worth 40 points. In no case could more than 40 points total be earned for the HIE objective. We proposed the HIE Bi-Directional Exchange measure would be reported by attestation and would require a yes/no response. As we believe that fulfillment of this measure is an extremely high value action, a ''yes'' response would enable eligible hospitals and CAHs to earn the 40 points allotted to the HIE objective. We proposed that eligible hospitals and CAHs would attest to the following:

- Participating in an HIE in order to enable secure, bi-directional exchange of information to occur for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in

[1361] *https://academic.oup.com/jamia/article/25/9/1259/4990601:* ibid.

[1362] *https://pubmed.ncbi.nlm.nih.gov/27521368/:* Journal of the American Medical Informatics Association. 2017 Apr 1;24(e1):e103–e110. doi: 10.1093/jamia/ocw116. ''*Health Information Exchange Associated With Improved Emergency Department Care Through Faster Accessing of Patient Information From Outside Organizations*''.

[1363] *https://protect2.fireeye.com/url?k=d8978709-84c28e1a-d897b636-0cc47adb5650-e634c1ba410d0153&u=https://www.healthit.gov/sites/default/files/reports/finalsummativereportmarch_2016.pdf.*

exclusionary behavior when determining exchange partners.

- Using the functions of CEHRT to support bi-directional exchange with an HIE.

We believe it is appropriate for the new optional measure to serve as an alternative measure of performance on health information exchange since, in order to successfully meet the measure, an eligible hospital or CAH would be required to meet an overall standard of performance on health information exchange that is broader than the denominators and numerators of the current measures. To successfully attest to the new measure the eligible hospital or CAH must establish the technical capacity and workflows to engage in bi-directional exchange of information via an HIE for to occur for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments during the EHR reporting period. This includes enabling the ability to query for or receive health information to occur for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR, as well as enabling sending or sharing information for these patients regardless of known referral or transition status, or the timing of any potential transition or referral. The proposed requirement to enable querying for or receiving health information for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments is broader than the current Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, which includes only new patients and known transitions or referrals received that occur during the EHR reporting period. Similarly, the proposed requirement to enable sending or sharing information for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments represents a broader scope than the current Support Electronic Referral Loops by Sending Health Information measure which includes only known transitions of care or referrals made that occur during the EHR reporting period. This proposed requirement is likewise more expansive than the denominators of either measure.

Relative to the numerators for the current measures, the new optional measure would require that bi-directional engagement be enabled for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments during the EHR reporting without exclusion, exception, or allowances made for partial credit. This is similar to achieving a score of 100 percent on both the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, while additionally completing required actions for additional exchange cases not included in the existing denominators. Finally, while we believe this optional measure would establish a high-performance standard with respect to information sharing, we also believe that availability of this optional measure would reduce current reporting burden associated with the program, as eligible hospitals or CAHs choosing to report on the measure would not be required to report on the two existing numerator/denominator measures.

To successfully attest to this measure, the eligible hospital or CAH must use the capabilities defined for CEHRT to engage in bi-directional exchange via the HIE, which includes capabilities which support exchanging the clinical data within the Common Clinical Data Set (CCDS) or the United States Core Data for Interoperability (USCDI). This is consistent with the existing measures under the Health Information Exchange objective, which require the use of CEHRT to create a Consolidated Clinical Document Architecture (C–CDA) document, and support the exchange of the clinical data within the CCDS or the USCDI. We believe there are numerous certified health IT capabilities which can support bi-directional exchange with a qualifying HIE. For instance, participants may interact with an HIE by using technology certified to the criterion at § 170.315(b)(1) to transmit C–CDAs to the HIE. Participants could also utilize API technology certified to either the criterion at § 170.315(g)(8) or (g)(10), as finalized in the ONC 21st Century Cures Act final rule (85 FR 25742), to enable an HIE to obtain data in the CCDS or USCDI from a participant's EHR. Additional certified health IT modules may also support exchange of information with an HIE for transitions of care, including modules certified to certification criteria at § 170.315(g)(7), ''Design and performance—Application access—patient selection,'' and (g)(9), ''Design and performance—Application access—all data request,'' which support information exchange via API; the certification criterion at § 170.315(e)(1) ''View, download, and transmit to 3rd party'' which supports patient access to their information; and the certification criterion at § 170.315(g)(6) ''Consolidated CDA creation performance'' which supports creation of a summary of care record. We recognize that HIEs are currently interacting with health care providers using certified health IT in a variety of ways, and believe that we should allow for substantial flexibility in how health care providers use certified health IT to exchange data using an HIE.

Furthermore, an eligible hospital or CAH attesting to these three statements would not be required to use all of the relevant certified health IT modules, as previously described, to support their connection with an HIE, nor must a connection with an HIE be solely based on certified health IT modules. For instance, a provider's EHR could generate a C–CDA using a certified health IT module, and subsequently transmit that document to an HIE using technology that is not part of a certified health IT module. Such an approach would be acceptable for attesting to the third proposed attestation statement requiring the use of CEHRT to support the measure.

We note that none of the actions required to attest to this measure are intended to conflict with a patient's rights or covered entities' (for example, health care providers) requirements/responsibilities under the HIPAA Privacy Rule, as set out at 45 CFR parts 160 and 164. We also understand that different HIEs that enable exchange in the manner described may have different policies related to confidentiality of patient information based on local circumstances and requirements. Nothing in the attestation statements for this measure are intended to conflict with individual HIE policies that may exist in these areas, or prevent eligible hospitals or CAHs from complying with these policies as a condition of their participation in the HIE.

We invited comments on our proposal, and whether commenters believe such an optional measure would incentivize eligible hospitals and CAHs to participate in HIEs while establishing a high-performance standard for sharing information with other health care providers.

Finally, while our proposed attestation statements for this measure do not explicitly refer to participation in a health information network, or partnering with a health information network that participates in the Trusted Exchange Framework and Common Agreement (TEFCA) described in section 4003 of the 21st Century Cures Act, we recognize that this is likely to be an important way for eligible hospitals and CAHs to enable bi-directional health information exchange in the future. We will continue to explore ways to provide further guidance and/or update this measure to align with the use of health information networks that participate in the TEFCA in the future. For more information on current developments related to the TEFCA, we refer readers to *www.HealthIT.gov/TEFCA.*

Comment: The majority of comments supported the addition of the HIE Bi-directional exchange measure. One stated that the ongoing capability for bi-directional exchange, and use of such a capability, are critical to advancing effective interoperability. Several commenters supported that this measure would be reported via attestation and were encouraged to see CMS' acknowledgement that this measure could align with the ONC efforts on the Trusted Exchange Framework and Common Agreement (TEFCA). Other commenters agreed that this measure will encourage bi-directional exchange of health information with community partners to promote care coordination for patients with chronic conditions and complex care needs. Several commenters concurred with our rationale that the new measure can support robust health information exchange while minimizing the burden on hospitals and patients to be individually accountable to facilitate exchange via multiple connections.

Response: We appreciate the support from commenters on the addition of this measure.

Comment: Some commenters suggested that CMS should take into consideration the fact that there are care settings that may lack certain technical capabilities and struggle with bi-directional exchange of patients' electronic health information compared to Promoting Interoperability Program participants.

Response: We understand that not all eligible hospitals and CAHs may be able to report this measure in CY 2022 which is why we proposed to make this an alternative measure to the two existing HIE measure. We encourage bi-directional exchange and will be monitoring the uptake of this measure to determine future policies surrounding this measure.

Comment: A commenter asked that we clarify that, while HIE participation must ''enable secure, bi-directional exchange of information to occur for all unique patients . . . and all unique patient records stored or maintained in the EHR . . .'', that exchange of patient summaries or other patient data need not occur for all such patients, only that it can occur as needed or requested. Another commenter expressed concern that the proposed bi-directional engagement measure would have to be enabled for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department and all unique patient records stored or maintained in the EHR for those departments during the EHR reporting period. The commenter asked if there would be no exclusions, exceptions or allowances made for partial credit.

Response: The first attestation statement, as proposed, would require an eligible hospital or CAH to enable bi-directional exchange for all of an eligible hospital's or CAHs patient records. Enabling bi-directional exchange does not mean that an eligible hospital or CAH would be required to conduct information transactions that are not clinically necessary. Rather, it means that an eligible hospital or CAH has established the capabilities necessary to complete exchanges of information for their patients at the appropriate time. We also decline to provide partial credit for this measure as partial performance would not meet the goals of the measure. Our goal in proposing this measure is to incentivize the high standard of performance on health information exchange which can be achieved by establishing robust, bi-directional exchange capabilities facilitated by an HIE. We do not believe that allowing an eligible hospital or CAH to satisfy the measure based on a partial threshold would be consistent with incentivizing a high performance standard for the exchange of health information.

Comment: A commenter asked that we clarify that, if such a provider or vendor-specific network connects with a regional or national exchange framework that enables connection across ''a broad network of unaffiliated exchange partners,'' whether such a connection would satisfy the attestation.

Response: For purposes of this measure and its attestation statements, the term ''HIE'' broadly refers to arrangements that facilitate the exchange of health information, and may include arrangements commonly denoted as exchange ''frameworks,'' ''networks,'' or using other terms. We understand that under some arrangements, HIEs or networks may partner with other network entities in order to extend their reach. Such arrangements would qualify to meet the intent of the second statement regarding sharing across unaffiliated providers.

Comment: A commenter stated that in their hospital C–CDAs come in and count as received, and then they generate responses and send out for follow-up post discharge. The bi-directional HIE which they are a part of currently is a pull and not a push exchange for all organizations. The commenter requested more detail on this measure to assist in understanding if this measure is a feasible option for providers using an EHR-specific vendor network for some connections, and a Health Information Service Provider (HISP) to connect with organizations that use different vendors.

Response: We stated in the proposed rule (86 FR 25633) that in order to attest successfully to the new measure the eligible hospital or CAH must establish the technical capacity and workflows to engage in bi-directional exchange of information for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments during the EHR reporting period. This includes enabling the ability to query or receive health information on all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments, as well as enabling sending or sharing information for these patients regardless of known referral or transition status, or the timing of any potential transition or referral. Furthermore, we clarified in the preamble of the FY 2022 IPPS/LTCH proposed rule (86 FR 25631 through 25634) that an eligible hospital or CAH attesting to these three statements would not be required to use all relevant certified health IT modules to support their connection with an HIE, nor must a connection with an HIE be solely based on certified health IT modules. For instance, a provider's EHR could generate a C–CDA using a certified health IT module, and subsequently transmit that document to an HIE using technology that is not part of a certified health IT module.

Regarding the commenter's example, provided the eligible hospital or CAH

successfully attested to the first attestation statement regarding bi-directional exchange for patients, and that the use of the HISP allowed the eligible hospital or CAH to successfully attest to the elements in the second attestation statement regarding sharing information across a broad network of unaffiliated exchange partners, including those using disparate EHRs, the participant would be able to successfully attest to the measure. The measure does not limit eligible hospitals or CAHs to the use of a single solution for all instances of bi-directional exchange.

Comment: A commenter stated that we should specifically limit any interoperability incentives to non-profit state or local HIEs which have state or locality-based governance, are non-profit, and which have shown that these HIEs are available to any healthcare provider of any type, including schools, jails, group homes, and shelters serving the underserved or mentally ill. These HIEs should be required to have a physical presence in each state. The commenter stated that the HIEs should not be preferentially affiliated with any EHR vendor and CMS should encourage these HIEs to serve as public health data utilities.

Response: We appreciate the commenter's focus on these types of HIEs. However, we decline to add additional restrictions on the types of HIEs that can qualify for the measure as our goal is broad inclusion of HIE arrangements that facilitate robust exchange of health information in alignment with the existing HIE measures. We believe the second attestation statement requiring HIEs to support exchange across a ''broad network of unaffiliated exchange partners, including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners,'' addresses concerns that the measure would incentivize use of HIEs that exclude certain providers.

Comment: A commenter suggested that it would be helpful if we provide examples of the types of transactions we see as pertinent to this measure.

Response: We take a broad view of the types of transactions applicable to this measure. As stated in the preamble of the FY 2022 IPPS/LTCH proposed rule (86 FR 25631 through 25634), we believe there are numerous certified health IT capabilities which can support bi-directional exchange with a qualifying HIE.

Comment: Several commenters asked that we clarify what types of audit evidence are expected for this measure.

Response: Suggested documentation would include the following: A dated report or screenshot that documents successful receipt and transmission of patient data via the entity providing health information exchange services. Any such documentation should include evidence to support that it was generated for that eligible hospital or CAH's system (for example, identified by National Provider Identifier (NPI), CMS certification identification number, hospital name, etc.) and/or letter, email, or other documentation from the entity providing health information exchange services that confirm participation of the eligible hospital or CAH, the date of on-boarding, a description of services provided, and a description of exchange network participants (for example, number/type of participating providers). Other types of documentation could also include letter, email, or other documentation from the eligible hospital or CAH's CEHRT vendor confirming a connection between the hospital's CEHRT and an entity providing health information exchange services, the date of on-boarding, a description of services provided, and a description of exchange network participants (for example, number/type of participating providers) for the duration of the EHR reporting period.

Comment: Many commenters requested that CMS define ''HIE''. One stated that the undefined term could exclude organizational models that might not be self-identified or otherwise identified as HIEs. The commenter believes that the measure should be expanded to ''HIEs, exchange frameworks, or other organizations focused on bidirectional health information exchange''. In defining HIEs, commenters also suggested that CMS consider cross-referencing the definition of HIEs and HINs established by ONC in 45 CFR 171.102.

Response: We appreciate the commenters' request for clarification. The term ''HIE'' is intended to refer broadly to arrangements that facilitate the exchange of health information, and may include arrangements commonly denoted as exchange ''frameworks,'' ''networks,'' or using other terms. To satisfy the measure, an HIE or other exchange network must support eligible hospitals and CAHs by fulfilling the requirements of the attestation statements, to include providing the capabilities specified under attestation statement 1 to allow an eligible hospital or CAH to enable bi-directional exchange for all of an eligible hospital's or CAHs patient records, and meeting the standard specified under attestation statement 2 related to facilitating non-exclusionary exchange. The attestation statements proposed for the purposes of this bi-directional exchange measure are intended to reward providers for engaging in robust information exchange through HIEs with measure-specific characteristics, which we believe are beyond the minimum necessary for an individual or entity to meet the functional definition of HIN/HIE established by ONC in 45 CFR 171.102. Thus, the attestations simply refer to the provider's participation in the HIE and a measure-specific set of capabilities from the HIE.

Comment: A commenter requested that CMS clarify if ''HIE'' includes exchange frameworks and networks as defined in ONC's information blocking regulations and/or if ''HIE'' includes other organizations focused on bi-directional health information exchange. The commenter suggested that we need to work with ONC to ensure that CEHRT requirements for EHRs are aligned with the proposed new measure.

Response: As stated previously, for purposes of this measure and its attestation statements, the term ''HIE'' broadly refers to arrangements that facilitate the exchange of health information, and may include arrangements commonly denoted as exchange ''frameworks,'' ''networks,'' or using other terms. The attestation statements proposed for the purposes of this bi-directional exchange measure are intended to reward providers for engaging in robust information exchange through HIEs with measure-specific characteristics, which we believe are beyond the minimum necessary for an individual or entity to meet the functional definition of HIN/HIE established by ONC in 45 CFR 171.102. Thus, the attestations simply refer to the provider's participation in the HIE and a measure-specific set of capabilities from the HIE. Regarding alignment with ONC's Health IT Certification Program, as discussed in the proposed rule we believe that health IT certified to a number of certification criteria specified under the CEHRT definition could support exchange with an HIE under this measure (86 FR 25633).

Comment: A commenter requested confirmation that the term ''all unique patient records stored or maintained in the EHR for these departments'' does not include a technical requirement to support receipt of a query for a C–CDA from an HIE. The commenter indicated there is no ONC certification requirement to support this type of query, so requiring it of health care providers before the technology is

widespread across the software development industry will create a very significant issue and threaten the ability of those providers to comply.

Response: The first attestation statement, regarding enabling secure, bi-directional exchange, does not prescribe that query functionality must be used among HIE participants. The ability for CEHRT to send a C–CDA to an HIE for every patient encounter, transition or referral, and the ability to retrieve a C–CDA from an HIE when a patient arrives for an encounter, referral or transition, using CEHRT, would satisfy the functional requirements described in the attestations.

Comment: A commenter encouraged CMS to continue to offer eligible hospitals and CAHs additional options and flexibility in meeting interoperability objectives. The commenter recommended that CMS work closely with ONC to ensure forward movement toward establishing the TEFCA. The commenter also recommended that the measure ''Engagement in Bi-directional Exchange Through Health Information Exchange (HIE)'' remain optional and that in addition to the measure's base 40 points, CMS consider bonus points for this measure.

Response: We appreciate the suggestions and may consider them in future rulemaking.

After consideration of the comments that we received, we are finalizing our proposal to add the HIE Bi-Directional Exchange Measure to the Medicare Promoting Interoperability Program as optional and worth 40 points beginning with the EHR reporting period in CY 2022. This measure will be an alternative to reporting on two existing HIE objective measures: The Support Electronic Referral Loops by Sending Health Information measure (42 CFR 495.24(e)(6)(ii)(A)) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (42 CFR 495.24(e)(6)(ii)(B)). Eligible hospitals and CAHs may either report the two existing measures and associated exclusions OR may choose to report the new measure. The HIE Bi-Directional Exchange measure will be worth 40 points. In no case will more than 40 points total be earned for the HIE objective. The HIE Bi-Directional Exchange measure will be reported by attestation and require a yes/no response. Eligible hospitals and CAHs will attest to the following:

- Participating in an HIE in order to enable secure, bi-directional exchange of information to occur for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.
- Using the functions of CEHRT to support bi-directional exchange with an HIE.

We are finalizing the corresponding changes to the regulation at 42 CFR 495.24(e)(6)(ii)(C).

6. Modifications to the Public Health and Clinical Data Exchange Objective

a. Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41637 through 41645, 41665 through 41667), for the Public Health and Clinical Data Exchange Objective, we finalized that eligible hospitals and CAHs must report on any two measures of their choice from the following 6 measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Electronic Reportable Laboratory Result Reporting. We also finalized that an eligible hospital or CAH must submit a yes/no response for any two measures to earn 10 points for the objective. Failure to report on two measures or submitting a ''no'' response for a measure will earn a score of zero. In addition, there are exclusions available for each of the measures. If an exclusion is claimed for one measure, but the eligible hospital or CAH submits a ''yes'' response for another measure, they would earn the 10 points for the Public Health and Clinical Data Exchange objective. If an eligible hospital or CAH claims exclusions for both measures they select to report on, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure under the Provider to Patient Exchange objective.

The Medicare Promoting Interoperability Program for eligible hospitals and CAHs has been an important mechanism for encouraging healthcare data exchange for public health purposes through the Public Health and Clinical Data Exchange Objective. But in an attempt to reduce burden, we previously stated our intention to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022 (83 FR 41665). Many commenters strongly opposed this potential policy change noting that the inclusion of this objective incentivizes health care providers to share data with public health agencies (83 FR 41666). In response to these comments, we stated that we would continue to monitor the data we compile specific to the public health reporting requirements and take the commenters' concerns into consideration related to future actions (83 FR 41667). Effective responses to public health events, such as the COVID–19 PHE, require fast, accurate exchange of data between health care providers and Federal, State, and local public health agencies (PHAs). Health care providers collect these data for patient care and PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

While our current approach has encouraged healthcare systems to stand up some of these capabilities, significant gaps remain, and in the absence of stronger incentives, it will be difficult to stand up the comprehensive data exchange needed for future public health response. Thus, we believe that a more assertive approach is needed.

b. Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective

At 86 FR 25634 through 25638 we proposed to require four of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the EHR reporting period in CY 2022: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. We proposed corresponding changes to the regulation text at 42 CFR 495.24(e)(8)(ii). These four measures would put PHAs on better footing for future health threats and a long-term COVID–19 pandemic recovery by strengthening three important public health functions: (1) Early warning surveillance, (2) case surveillance, and (3) vaccine uptake. Requiring these measures would enable nationwide syndromic surveillance for early warning of emerging outbreaks and threats; automated case and laboratory reporting for fast public health response; and local and national visibility on immunization uptake so PHAs can tailor vaccine distribution strategies.

Comment: Many commenters supported the proposed modifications

of this objective and concurred that the proposed modifications to the objective could better prepare the healthcare system for future health threats and long-term pandemic recovery by strengthening critical public health functions. Several commenters strongly supported raising the bar for Public Health reporting and updating the Public Health and Clinical Data Exchange Objective with regard to participating hospitals implementing Electronic Case Reporting, Electronic Reportable Laboratory Result Reporting, Syndromic Surveillance Reporting and Immunization Registry Reporting. These four measures all have mature and well-adopted standards and should represent the floor for all Public Health reporting.

Response: We thank commenters for their support.

Comment: Many commenters did not support requiring four measures in CY 2022. One stated that it is infeasible to require four measures for CY 2022 and does not accurately reflect current PHA data systems capabilities and the corresponding reporting landscape for hospitals and CAHs. Several commenters recommended that CMS use a flexible, staged approach to scoring the four measures it proposes to require. Many commenters supported an alternative approach that would require three of the four measures for CY 2022 and all four measures required in CY 2023. A few commenters encouraged CMS to provide sufficient lead time for implementation. A commenter stated that the proposed timeline is extremely burdensome. Several commenters mentioned the lack of public health reporting infrastructure with one stating that hospitals should not be penalized for the lack of critical public health reporting infrastructure, and those who make a good faith effort to report despite these challenges should be eligible to achieve meaningful use of EHR technology. Another commenter stated that hospitals and other healthcare facilities have been under tremendous stress from responding to the COVID–19 PHE, and this would divert resources to handle the increased reporting requirements so the commenter suggested delaying the requirement to add two additional measures until at least CY 2023. A few commenters indicated that many states are not ready to support this proposal because they rely on local networks instead of statewide registries.

Response: Currently, PHAs in all 50 states accept electronic case report data, syndromic surveillance data, immunization registry data, and electronic lab report data. We understand that infrastructure gaps may exist and that different public health jurisdictions have different capabilities to process and use this data. The CDC is supporting PHAs to rapidly advance their capabilities through the Epidemiology and Laboratory Capacity cooperative agreement,[1364] and through the Data Modernization Initiative.[1365] Importantly, the measures themselves have exclusions that account for this varied landscape. Eligible hospitals and CAHs that could report to a PHA that has not declared readiness can still earn points towards the Public Health and Clinical Data Exchange Objective, if they are at option one of active engagement (completed registration to complete data), and ready to implement option two of active engagement (testing and validation) as soon as the PHA does declare readiness The three options are Active Engagement Option 1 includes completing registration to submit data, Active Engagement Option 2 includes testing and validation, and Active Engagement Option 3 includes production (80 FR 62818). Thus, eligible hospitals and CAHs will not be penalized for the lack of public health infrastructure. While hospitals and healthcare facilities are currently challenged by COVID–19, each of these reporting requirements provides public health with information that is essential to the public health response to COVID–19 and that will be essential for managing and responding to current and future health threats.

Comment: A commenter encouraged CMS to update the specifications for each of the required registries to allow a provider to claim an exclusion if their state does not have, or cannot support, one or more of the four required registries: Electronic Case Reporting, Electronic Reportable Laboratory Result Reporting, Syndromic Surveillance Reporting, or Immunization Registry Reporting.

Response: All four of the required measures include exclusions that address jurisdictions in which the PHA does not support the reporting type: Electronic Case Reporting, Electronic Reportable Laboratory Result Reporting, Syndromic Surveillance Reporting and Immunization Registry Reporting.

Comment: A commenter urged CMS to work more closely with its Federal partners, including CDC and ONC, to align requirements for public health data collection and reporting and the requisite health information technology capabilities. Further the commenter stated that given the federated approach to public health in the U.S., CMS needs to consider the disparate state-level public health data collection and reporting requirements.

Response: We thank the commenter for their support and agree that CMS, CDC, and ONC should work together closely to align the requirements for public health data collection and the requisite health information technology capabilities. The three agencies are already collaborating closely on these critical issues. We recognize that the CDC Data Modernization Initiative has efforts towards streamlining requirements as much as possible within the federated approach to public health.

Comment: A commenter encouraged CMS to define ''active engagement'' in these measures to reflect that data sharing must be occurring rather than the hospital solely having the intent of sharing data or still conducting onboarding processes with public health authorities. This approach will also help replace inefficient paper-based mechanisms to give authorities, clinicians, and patients more complete, timely data.

Response: We thank the commenter for their suggestion and may consider revising our active engagement definitions that we finalized in the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864) in future rulemaking.

Comment: Some commenters stated that they will have to submit a hardship exception application for 2022 reporting because they cannot satisfy the proposed requirements.

Response: We remind readers of the availability of exclusions for all of the required measures: Electronic Case Reporting, Electronic Reportable Laboratory Result Reporting, Syndromic Surveillance Reporting and Immunization Registry Reporting. In addition, eligible hospitals and CAHs may submit a hardship exception application. For more information, go to *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj_Hardship.*

After consideration of the public comments we received, and as discussed in greater detail in the following sections of the preamble, we are finalizing our proposal to require four of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the EHR reporting period in CY 2022: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. We are also finalizing

[1364] *CDC—ELC Cooperative Agreement—DPEI—NCEZID.*

[1365] Data Modernization Initiative | CDC.

corresponding changes to the regulation text at 42 CFR 495.24(e)(8)(ii), as proposed.

(1) Syndromic Surveillance Reporting Measure

Syndromic surveillance provides PHAs with a timely way to detect, understand, and monitor health events using data from EHRs in emergency departments (EDs) and urgent care centers. By tracking patient symptoms and discharge diagnoses, PHAs have a strong early warning system that allows them to identify, monitor, characterize, and respond to novel and continuing health events (for example, influenza, drug overdoses, vaping associated lung injuries, natural disasters, bioterrorism threats, and COVID–19) in near real time. Syndromic surveillance also provides real-time information for health events that are not supported by case reporting or laboratory reporting, such as injuries, suicidal ideation, non-reportable infectious diseases, and subtle health changes that are undiagnosed but can be detected by automated monitoring of chief complaint narratives and population-level trends. Syndromic surveillance relies on the secondary use of EHR data that supports delivery of care, enabling an efficient and cost-effective way to identify and characterize public health threats. The provision of these data requires no action from a health care provider, with data exchange automated from the EHR.

Syndromic surveillance has been critical for responding to the COVID–19 PHE, enabling situational awareness for decision makers at local, state, and national levels. The National Syndromic Surveillance Program (NSSP) is the primary mechanism for national-level syndromic surveillance in the United States. State and local stakeholders are critical end users and facilitate onboarding of hospitals, administering access to data, and monitoring data quality. CDC provides tools and assistance to facilitate these functions (for example, message mapping guides, standards, onboarding assistance, and data quality resources). As of July 13, 2021, nearly 6,000 healthcare facilities covering 50 states and the District of Columbia contribute data to NSSP, representing approximately 70% of all U.S. nonfederal EDs.[1366] With approximately 3 in 10 nonfederal hospitals not participating in NSSP, there remain major gaps in syndromic surveillance coverage, leaving blind spots in the ability of local, state, and Federal PHAs to adequately prepare for, and respond to, emerging local and regional public health events.

We proposed to make Syndromic Surveillance Reporting a required measure under the Public Health and Clinical Data Exchange Objective in the Medicare Promoting Interoperability Program (86 FR 25634 through 25635) beginning with the EHR reporting period in CY 2022 to expand the coverage of syndromic surveillance to every region in the United States, help healthcare facilities and PHAs better prepare for emerging health events, and provide critical national early warning capabilities necessary for swift response and control of outbreaks, such as COVID–19. Requiring eligible hospitals and CAHs to report on participation in syndromic surveillance is anticipated to significantly increase hospital engagement with a PHA to submit syndromic data, particularly from the ED. The public health benefit of syndromic surveillance would be strengthened as the proportion of participating hospitals increases, that is, as more hospitals participate, there are more comprehensive and timely data with fewer gaps and the capability itself becomes better at detecting emerging threats. ED data are often among the earliest indicators of emerging health threats. As demonstrated with the COVID–19 pandemic, surveillance data from EDs often foreshadow a rise in the percent of persons testing positive, case incidence and deaths, and can focus assessments on relevant populations, such as age groups, racial or ethnic groups, persons experiencing homelessness, persons with recent travel history, or recently vaccinated patients. Increased coverage would also improve coordination with PHAs, providing hospitals with the ability to respond to the emergence of new health threats and modify their treatments, preparedness planning, and facility staffing accordingly. Converting the Syndromic Surveillance Reporting measure from optional to required would not pose a significant burden on hospitals; as hospitals in all 50 states already participate in NSSP, the necessary infrastructure for wider adoption is already in place. More than two-thirds of nonfederal EDs participate in NSSP, demonstrating the feasibility of participation for a broad range of facilities and systems. Many nonparticipating facilities are part of larger health networks that have facilities already participating in NSSP.[1367] CDC's robust technical assistance program through NSSP and the network of State and local stakeholders would provide direct assistance to address technical challenges. While setting up the syndromic surveillance capability requires some initial implementation effort from the hospital, there is no significant ongoing burden, as the EHR vendor sets up and maintains the data feed.

In addition, upon further review of the current description for the Syndromic Surveillance Reporting measure, we believe the reporting requirement should include ED data only. Data from the ED setting are the most important based on clinical severity and there is existing infrastructure among hospitals and PHAs to make this a feasible policy to implement. While urgent care data are valuable, adding a requirement for reporting in that setting at this time could impose unnecessary burden on some healthcare facilities and PHAs; however, the reporting of urgent care data remains an option and could be required at the discretion of the PHA.

The current description of this measure is as follows: The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting. We proposed to change the setting for which data is required to be submitted from urgent care to the emergency department, place of service code 23, beginning with the EHR reporting period in CY 2022. We proposed to codify this change at 42 CFR 495.24(e)(8)(ii)(A). We also proposed that the first exclusion for this measure be modified to remove the reference to urgent care. The other two exclusions are unchanged. We proposed to modify the first exclusion at 42 CFR 495.24(e)(8)(iii)(A)(1).

Comment: Some commenters stated that there are major gaps in syndromic surveillance coverage such as inadequate state health information technology infrastructure and states being unable to receive electronic data and objected to making the measure required in 2022.

Response: While syndromic surveillance reporting is well-established, gaps in coverage remain and are a key consideration for strengthening public health reporting requirements. In the context of the current COVID–19 pandemic response, a timely reduction of these coverage

[1366] Overview of the National Syndromic Surveillance Program (NSSP), *https://www.cdc.gov/nssp/overview.*

[1367] Overview of the National Syndromic Surveillance Program (NSSP), *https://www.cdc.gov/nssp/overview.html.*

gaps serves to enhance PHAs capacity to perform surveillance and guide response. Further, we remind readers of the availability of 3 exclusions for this measure, two of which address gaps resulting from PHAs declaring that they are not yet capable of receiving syndromic surveillance data.

Gaps in coverage for syndromic reporting can be due to hospitals not reporting to PHAs that are able to receive syndromic data, and gaps can also be created when PHAs are unable to receive syndromic data. Requiring this measure is expected to improve coverage in areas where PHAs attest readiness to receive syndromic data. Eligible hospitals and CAHs that would report to a PHA that has not declared readiness can still get credit towards the Medicare Promoting Interoperability Program as long as they are using active engagement option one and have registered with the PHA, but they must be ready move through the options for active engagement as soon as the PHA does declare readiness. Thus, eligible hospitals and CAHs will not be penalized for the lack of public health infrastructure.

Comment: A commenter stated that they disagreed with CMS' statement that the proposed public health reporting requirements would not pose a significant burden on hospitals because, at the time, 49 states were participating in the National Syndromic Surveillance Program (NSSP). To the contrary the commenter believed that state participation in NSSP is not an indicator of providers' burdens and does not reflect the degree to which EHRs are capable of meeting CMS' public health reporting measures. The commenter asserted that given the federated approach to public health in the U.S., CMS needs to consider the disparate state-level public health data collection and reporting requirements. The commenter stated that they are concerned about the proposal to not require syndromic reporting from urgent care given the importance of syndromic surveillance across settings. For example, many patients turned to alternative sites of care during the PHE out of concern for possible exposure to COVID–19 in emergency departments and other hospital settings. Finally, the commenter stated that public health surveillance was previously expected to improve due to increased use of EHRs and electronic exchange of health information; however, additional health information technology capabilities and applications are needed to further ensure syndromic surveillance data collection across multiple settings of care, reporting and exchange. The nation needs real-time data for syndromic surveillance, providing an upstream alternative to identifying cases before tests can detect them or patients are hospitalized. This includes collecting data across multiple settings of care, such as urgent care, clinics, physicians' offices, and telehealth visits.

Response: Syndromic surveillance reporting is a well-established activity and the standardized message is well supported by EHR systems, with more than 266 Certified Health IT Modules offering the capability certified to the ''Transmission to public health agencies—syndromic surveillance'' certification criterion at 45 CFR 170.315(f)(2).

With more than 3,000 non-Federal emergency departments in the United States already participating in the National Syndromic Surveillance Program and 45 states with more than 50% of their emergency department facilities already providing syndromic surveillance data in accordance with well-established data standards, adoption of this activity is strong. However, the remaining gaps in coverage limit public health's ability to detect and monitor health events in the community. This was particularly evident during the COVID–19 pandemic, when syndromic surveillance data from emergency departments provided an important early indicator of population-level COVID–19 activity. Long-term, the goal is to expand syndromic surveillance capabilities toward a broad array of clinical settings, and some PHAs already incorporate urgent care data into their surveillance. However, hospital emergency departments remain a core focus and offer broad representation of patients with acute or severe illness presenting to urgent care facilities. This revision to this measure does not reduce the ability of PHAs to receive syndromic data from urgent care facilities.

Comment: A commenter stated that the Syndromic Surveillance Reporting measure should include more than just the emergency department setting. In doing so, public health data would be more comprehensive, as most of the population would use a primary care or urgent care setting to address the potential spread of communicable diseases. Another disagreed with the removal of urgent care settings from Syndromic Surveillance reporting as this setting is a data critical source and should continue to be included.

Response: Long term, NSSP intends to expand syndromic surveillance capabilities toward a broader array of clinical care settings, and some PHAs have begun to accept data from settings such as urgent care and primary care. However, with limited public health resources, hospital emergency department data offers broad representation and national coverage, and remains a core focus for syndromic surveillance. As finalized, this measure does not reduce the ability of PHAs to receive, nor require, data from urgent care facilities, primary care facilities, or other clinical settings.

After consideration of the public comments we received, we are finalizing our proposal to make Syndromic Surveillance Reporting a required measure under the Public Health and Clinical Data Exchange Objective in the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022. We are finalizing our proposal to change the setting for which data is required to be submitted from urgent care to the emergency department, place of service code 23, beginning with the EHR reporting period in CY 2022. We are codifying this change as proposed at 42 CFR 495.24(e)(8)(ii)(A). We are also finalizing that the first exclusion for this measure is modified to remove the reference to urgent care. The other two exclusions are unchanged. We are modifying the first exclusion as proposed at 42 CFR 495.24(e)(8)(iii)(A)(1).

(2) Immunization Registry Reporting Measure

Immunizations are considered one of the ten great public health achievements and have resulted in declines in cases, hospitalizations, deaths, and health care costs associated with vaccine preventable diseases.[1368] The benefits and value of immunizations are realized when public policy, health systems, and community-based intervention efforts are working in coordination. Ensuring the coordination of these efforts can achieve high immunization coverage is dependent on the availability of timely, accurate, and complete information on vaccinations received by individuals in a population.

Immunization registries (also called immunization information systems or IIS) are powerful tools that allow collaboration between vaccine providers and public health agencies and enable coordination of population-based interventions. Immunization registries are confidential, population-based, computerized systems that record all vaccination doses administered by participating health care providers for individuals residing within a particular

[1368] Ten Great Public Health Achievements–United States, 2001—2010 (*cdc.gov*)

jurisdiction. At the point of clinical care, an immunization registry can provide consolidated immunization histories to assist vaccine providers in determining appropriate patient vaccinations. At the population level, immunization registries provide data on vaccination coverage assessment and program operations and in guiding public health action to improve vaccination rates.

Currently, 50 states, the District of Columbia, 8 island territories, and 3 cities (New York City, Philadelphia, and San Diego) operate an immunization registry. CDC provides technical assistance and nationwide leadership to all State immunization registries to ensure the optimal use of immunization registries for determining vaccination coverage at local, State, and national levels. Immunization registries already have connections in place to capture administered doses in real-time for a substantial portion of the population, a process accelerated over the last eight years by the Promoting Interoperability Programs. According to data from the most recent CDC IIS Annual Report (2019) available, immunization registries currently hold demographics and immunization data on 95% of children 0–6 years, 82% of adolescents, and 60% of adults.[1369] While each State Immunization registry currently coordinates with health care providers and EHR systems to achieve interoperability and facilitate immunization reporting, varying State reporting policies limit the completeness and timeliness of records in immunization registries and the optimal use of immunization registries for determining vaccination coverage.

We proposed to make the Immunization Registry Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022 (86 FR 25635 through 25636) as it is critical for understanding vaccination coverage both at the jurisdiction level and nationwide and identifying where additional vaccination efforts are needed. Making standardized reporting to an immunization registry a required measure would provide an immediate benefit by increasing the COVID–19 vaccination records reported to these systems. Making the measure required would also improve the data quality of records in immunization registries and facilitate use of immunization registries for clinical decision support and tracking of vaccine administration and distribution.

We believe that making the Immunization Registry Reporting measure required, compared to the current option that allows a provider to choose this measure as one of two among six measures, would increase the reporting of immunization data by health care providers to public health agencies. Making the measure required is also critical for the COVID–19 vaccination response because it would provide a better view of the vaccines administered and distributed at national, State and local levels. This is a function that immunization registries currently provide for all public vaccines, but would be particularly important for COVID–19 vaccines. In addition to the COVID–19 vaccination response, there is an equally important need for routine vaccination coverage to increase. More complete data in immunization registries as a result of the required measure would also optimize the use of immunization registries to determine who has not been vaccinated, pockets of under vaccination, and identifying where interventions should be focused for routine and emergency response vaccines. Requiring the measure would reduce the regulatory and administrative burden health care providers experience when exchanging information with immunization registries.

We did not propose any changes to the description of the measure including any of the exclusions that we established at 42 CFR 495.24(e)(8)(iii)(B).

Comment: Many commenters supported the proposal to make the Immunization Registry Reporting measure required. Some commenters stated that vaccines are arguably the most critical tool to fight COVID–19 and any future pandemics. Others stated that knowledge of immunization status helps to inform diagnostic testing and diagnosis. With initial access to COVID–19 vaccination, many individuals received vaccine in non-traditional settings where their providers may not have access to the documentation. Several other commenters stated that routine immunizations have been deferred and/or missed altogether during the pandemic, and this shift to require the Immunization Registry Reporting measure would support stronger surveillance and awareness of immunization rates for all vaccines. Embedding immunization data exchange throughout public and private health care will help to ensure informed clinical decisions and data driven population health well into the future. The commenter stated that the broad availability of immunization data through real-time Electronic Health Record (EHR)-IIS query significantly lowers the burden (and cost) to providers in accessing immunization records and forecasts at the point of care. This functionality to query the IIS from within an EHR and receive back a consolidated record and forecast for immunizations due is currently available to health care providers in the vast majority of states across the country and is in the process of being developed in the remaining locations. This accelerated adoption of query functions across EHRs and IIS is due in large part to incentives provided through Meaningful Use/Promoting Interoperability Program. A commenter stated that immunization registries are critical for understanding the comprehensive view of a patient's immunization status, which is essential for health care providers to make recommendations for require vaccinations. Increasing use of immunization registries is one tactic to help increase immunization rates and improve population health.

Response: We appreciate the support for requiring this measure.

Comment: A commenter stated that immunization registries are critical for understanding the comprehensive view of a patient's immunization status, which is essential for providers to make recommendations for require vaccinations. Increasing use of immunization registries is one tactic to help increase immunization rates and improve population health.

Response: We thank the commenters for their support.

Comment: A commenter suggested that we should ensure there are exclusions available if there is not a state immunization registry available for a provider to report to. Additionally, CMS should survey the state immunization registries to determine if there is readiness at the state level to conduct this level of exchange.

Response: The commenter is correct that the exclusions that we established at 42 CFR 495.24(e)(8)(iii)(B) remain available. As we have stated previously, currently, 50 states, the District of Columbia, 8 island territories, and 3 cities (New York City, Philadelphia, and San Diego) operate an immunization registry.

After consideration of the public comments we received, we are finalizing our proposal to make the Immunization Registry Reporting measure a required measure under the

[1369] *https://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/2019-data.html.*

Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022.

(3) Electronic Case Reporting

Healthcare providers are required by State law to report certain diseases and conditions, a process called *case reporting,* which provides PHAs with data on approximately 120 diseases and conditions of public health significance.[1370] Case reporting is a vital and long-standing tool that PHAs use to prevent the spread of infectious diseases. Case reporting serves as early notification to PHAs for potential outbreaks, and includes information that enables PHAs to start contact tracing and other prevention measures. Case reports also include critical clinical information that would not be included in syndromic surveillance or laboratory reporting, and can help to illuminate the impact of comorbidities, treatments, and variable access to care. Information from the case reports can be used to further work on social determinants of health and ensure equal access to preventative care across populations. Electronic case reporting is the automated, real-time, bi-directional exchange of case report information between EHRs and PHAs. Electronic case reporting uses standard codes to trigger the transfer of relevant clinical data to PHAs for case investigation and follow-up. As of March 2021, most states do not require electronic submission of case reports as part of their regulations and case reporting often occurs through outdated manual methods (for example, fax, email, or phone), which results in delays, underreporting, and incomplete or inaccurate case data. Manual case reporting also imposes burdens on health care providers, taking staff time away from patients to submit case reports and comply with State reporting requirements. Electronic case reporting allows health care providers to fulfill mandated public health reporting requirements without imposing additional burden and disrupting the clinical workflow. This automated data exchange facilitates faster and more efficient disease tracking, case management, and contact tracing. Electronic case reporting provides more timely and complete data than manual reporting, including data on demographics, comorbidities, immunizations, medications, occupation, and other treatments.

Recent efforts by the CDC have sought to significantly improve the effectiveness of electronic case reporting through eCR. Now, a strategic initiative that allows for rapid adoption and implementation of electronic case reporting for COVID–19 (*https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting.html*). As part of this initiative, CDC and its partners have developed an eCR Now FHIR® Application to establish electronic case reporting capability in EHR systems using an application programming interface (API). The initiative also supports an electronic case reporting infrastructure that is helping to advance interoperability. This infrastructure supports sending electronic case reports to a shared service platform managed by the Association of Public Health Laboratories (APHL (*https://www.aphl.org/programs/informatics/pages/aims_platform.aspx*), and not directly to a PHA, which means that any health care provider that has implemented the specifications for eCR Now and connected to the APHL system also has a connection with every State PHA, many large local health departments, and some territories that are also connected.

This promotes nationwide interoperability and increases the availability of data for patients who may be traveling or spending time away from their home State. For example, if a patient is a resident of one State but seeks care in another State, this infrastructure will automatically route the case report to both states that would have jurisdiction over this report. This increases inter-jurisdictional reporting, allowing for more seamless case investigation at the national level.

As a result of the CDC effort to scale up eCR Now for COVID–19, all 50 states, the District of Columbia, Puerto Rico and 12 large local jurisdictions have connected to the eCR shared services platform and are currently receiving electronic case reports, with more than 8,800 healthcare facilities on board and 8.9 million reports for COVID–19 received by PHAs as of July 21, 2021.[1371] The eCR infrastructure is designed to rapidly scale for PHEs, such as COVID–19, but it is also enabled to currently support data transmission for 108 reportable conditions. While these are significant advancements in the adoption of electronic case reporting by healthcare providers, an accompanying policy incentive is needed to encourage continued adoption of electronic case reporting by health care providers at a national level.

We believe the uneven adoption of electronic case reporting creates a public health vulnerability. We proposed to make the Electronic Case Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022 (86 FR 25636 through 25637). We believe making this a required measure would accelerate development of electronic case reporting capabilities in EHR systems, reduce healthcare administrative burden of complying with State-mandated disease reporting requirements, provide regulatory clarity for EHR vendors, and improve the timeliness, completeness, and utility of case report data for PHAs.

We believe that requiring the Electronic Case Reporting measure would be feasible and beneficial for eligible hospitals and CAHs. This change would encourage EHR vendors to make electronic case reporting available to their customers, which would make adoption of this capability relatively straightforward for eligible hospitals and CAH. As described in the EHR Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62888), for purposes of this measure, eligible hospitals and CAHs must use a health IT module certified to the ''Transmission to public health agencies—electronic case reporting'' certification criterion at 45 CFR 170.315(f)(5). This certification criterion relates to how the health IT uses structured data within an EHR to trigger or indicate the generation of an electronic initial case report (eICR).[1372] Eligible hospitals and CAHs may then transmit the report in the manner specified by the case reporting requirements of the entity to which they are transmitting a report. In addition, ONC clarified earlier this year that in order for a Certified Health IT Developer to be certified to 45 CFR 170.315(f)(5), the developer may provide documentation of electronic case reporting implementation using the eCR Now FHIR application implementation guide to its ONC-Authorized Certification Body.

We believe that requiring the Electronic Case Reporting measure

[1370] CSTE State Reportable Condition Assessment page: *https://www.cste.org/page/SRCA.*

[1371] Healthcare Facilities in Production for COVID–19 Electronic Case Reporting | CDC.

[1372] For more information about this certification criterion, please see the Certification Companion Guide at *https://www.healthit.gov/test-method/transmission-public-health-agencies-electronic-case-reporting.*

would provide certainty to Certified Health IT Developers and facilitate an organized and industry-wide rollout of electronic case reporting capabilities. This change would encourage EHR vendors to make electronic case reporting available to their customers, which would make adoption of this capability relatively straightforward for eligible hospitals and CAHs.

We did not propose any changes to the description of the Electronic Case Reporting measure and the exclusions that we established at 42 CFR 495.24(e)(8)(iii)(C) will remain available.

Comment: Several commenters supported making the Electronic Case Reporting measure required for eligible hospitals and CAHs. The commenters believe this change has the potential to revolutionize the way local health departments investigate reportable communicable diseases. According to the commenter, under the current state, a significant amount of investigators' time is spent obtaining information already available in the patient's EHR, including critical data such as treatment information, hospitalization status, or race and ethnicity. Incentivizing electronic case reporting has the potential to eliminate these tedious and time-consuming tasks, both for investigators as well as hospital staff, such as infection preventionists, who typically supply this information. As a result, these skilled employees would be able to rededicate this time to actively preventing disease transmission, through activities such as contact tracing, thereby making our communities (and in the case of infection preventionists, health care facilities) safer places. Another commenter stated that Electronic Reportable Laboratory Result Reporting measure data is automatically processed into our disease surveillance system and is the primary method for all our notifiable conditions work and they supported making it a requirement. A commenter stated that the phenomenal success of the eCR Now program in the area of electronic Case Reporting has highlighted how focused support can rapidly expand electronic Public Health reporting. Additional programs with a similar approach focused on other Public Health programs could dramatically expand reporting in areas such as Newborn Screening, Vital Records and Birth Defect Reporting. As well, eCR Now is an excellent example of the role that systems can play in reducing the implementation burden for Public Health, healthcare organizations and HIT Vendors. The commenter strongly supported the development of additional infrastructure to promote interoperability in other Public Health program areas.

Response: We appreciate the commenters support for this proposal.

Comment: A commenter stated their belief that technology adoption for electronic case reporting to various agencies continues to mature, and recommended delaying a requirement to specifically participate in electronic case reporting for one more year. Another commenter stated that although their organization was one of the first adopters of electronic case reporting, they will need an extra year to implement certified health IT for electronic case reporting after the conclusion of the COVID–19 PHE. This commenter stated that the hardship lies disproportionately heavily on small, rural hospitals where technical staff are working under competing priorities. The commenter also stated the vendor-dependent coordination to local code mapping required for setting trigger codes, which takes coordination and time.

Response: Currently, all 50 states, DC, Puerto Rico, and several local PHAs accept data from electronic case reporting for COVID–19. We recognize that different public health jurisdictions have different capabilities to process and use this data; CDC is supporting PHAs to rapidly advance their capabilities. We note that CMS has included Electronic Case Reporting as an optional measure for hospitals and CAHs since 2015. Additionally, ONC has supported certified functionality for electronic case reporting through the ONC Certification Program for the same period. More recently, ONC clarified that Certified Health IT Developers' can certify to the criterion, ''Transmission to public health agencies—electronic case reporting'' at 170.315(f)(5) by providing documentation of support for eCR Now implementation. Given the need for case data by PHAs and the clear technology pathways for Certified Health IT Developers to support their eligible hospital and CAH clients, the proposed timeline of CY22 for implementation is both needed and feasible.

We reiterate that, public health has an urgent need for this data in order to respond to routine outbreaks and to be prepared for emergency response. We note that a number of developments in recent years have created opportunities to pursue electronic case reporting, such as the eICR CDA standard, which was first published in 2016, and the expanded architecture efforts for electronic case reporting implemented since 2018, giving EHR vendors and other stakeholders a variety of options for technology development.

Comment: A commenter suggested that we need to ensure FHIR APIs and electronic case reporting is in place prior to requiring the Electronic Case Reporting measure. As a result, the commenter recommended delaying making this requirement mandatory until CY2023.

Response: ONC's 21st Century Cures Act final rule updated certification criteria in the ONC Health IT Certification program related to the use of APIs. The API certification criteria at 45 CFR § 170.315(g)(10), as finalized in the 21st Century Cures Act final rule, requires the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard Release 4. Health IT developers must make certified technology meeting the new certification criteria available to customers by December 31, 2022.

Given the critical nature of getting to nationwide implementation of electronic case reporting, Certified Health IT Developers have options for how they support hospitals or CAHs to meet the 90-day EHR reporting period in 2022. For Certified Health IT Developers not already supporting electronic case reporting, these capabilities can be certified to the certification criterion for ''Transmission to public health agencies—electronic case reporting'' at § 170.315(f)(5) by providing their ONC-Authorized Certification Body documentation that sufficiently describes how the Health IT Module meets the functional requirements of the criterion and/or documentation of electronic case reporting implementation using the eCR Now FHIR application and the ability to meet paragraph (i) of this criterion. Certified Health IT Developers are encouraged to visit the 2015 Edition Cures Update Certification Companion Guide page (*https://www.healthit.gov/test-method/transmission-public-health-agencies-electronic-case-reporting*) for more information. With appropriate prioritization by Health IT Developers, implementation of eCR capabilities is achievable.

Comment: A commenter stated that based on discussions with their exchange partners, development of electronic case reporting is still in its infancy and more time is needed before this option should be required. The commenter respectfully requested the Electronic Case Reporting measure not be required for 2022.

Response: The Electronic Case Reporting measure has been an optional measure in the program since 2015, with corresponding certification

requirements from ONC. In addition, the eICR CDA standard was first published in 2016, and the developments in architecture have been implemented since 2018. During COVID–19, there have been rapid advances in support for electronic case reporting from national exchange networks. We acknowledge the commenter's point that electronic case reporting does not have nationwide adoption, which further serves to indicate the importance of a updating program requirements to further incentivize the adoption and use of this capability. Electronic case reporting is a long-standing need for public health and rapid implementation by healthcare organizations will lead to a more prepared data infrastructure for routine and emergency public health surveillance. We are committed to improving data exchange between public health and healthcare, and this final policy will promote rapid adoption of electronic case reporting to ensure that there is a more scalable infrastructure in place prior to the next pandemic or emergency response. Given the urgencies of the need for case data by PHAs and the clear need for improved bi-directional information flow between public health and healthcare, a timeline of 2022 is necessary for implementation by hospitals and CAHs.

Comment: An EHR vendor commented that all their products do not currently have the electronic case reporting functionality and suggested the following options: 1. Delay requiring the Electronic Case Reporting measure to the 2023 reporting year, 2. Add an exclusion for the 2022 reporting year for the clients of any EHR vendor that must complete software development work to provide the ONC certified Electronic Case Reporting functionality, OR 3. Make the Electronic Case Reporting requirement non-mandatory for 2022.

Response: There are exclusions for the Electronic Case Reporting measure that are based on the capability of PHAs. The need for electronic case reporting capability in EHR products has been long standing, and the need for PHAs to receive critical data for public health investigations has never been more apparent than now. As shown by the COVID–19 pandemic, where PHAs received significant missing and incomplete data from health care providers, an interoperable and scalable data stream from health care providers to public health is necessary. Many healthcare organizations had increased costs and challenges manually reporting data to public health, and the variability of formats and completeness posed a significant challenge in the nation's ability to respond to COVID–19. Further delaying the implementation of electronic case reporting capabilities will hinder the nation's preparedness for future emergency response.

After consideration of the public comments we received, we are finalizing our proposal to make the Electronic Case Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022.

(4) Electronic Reportable Laboratory Result Reporting Measure

State laws and regulations require laboratories to report certain diseases and conditions identified by testing to State and local PHAs. Electronic laboratory reporting (ELR) is the automated transmission of reports from laboratories to State and local PHAs. ELR produces faster and more complete information than manual reporting, reduces the burden of submission to PHAs, and eliminates opportunities for data entry error. ELR facilitates efficient case investigation, contact tracing, identification of hot spots, and other core public health functions. Because ELR requires essential fields, PHAs are less likely to request follow up information when receiving reports via ELR feeds, further reducing burden on laboratories.

Prior to the COVID–19 pandemic, more than 90% of laboratory reports sent to PHAs were submitted via ELR; the bulk of this reporting came from commercial laboratories. Hospital laboratories were less likely to utilize ELR data feeds relative to commercial laboratories, relying on other means to report results. The COVID–19 pandemic posed a tremendous challenge to the nation's laboratory and testing infrastructure, and rates of ELR to PHAs declined as COVID–19 testing increased, a multitude of tests (for example, point-of-care tests) entered the market, and non-traditional testing sites (for example, drive thru testing sites) where ELR is not available were utilized. Throughout the pandemic, the subset of hospital laboratories, while still a relatively small portion of overall testing volume, continued to lag in ELR implementation relative to larger commercial and clinical laboratories. A CDC-Association of Public Health Laboratories (APHL) collaboration has enabled the reporting of COVID–19 laboratory data through the APHL Informatics Messaging Services (AIMS) platform. Using AIMS, PHAs can submit essential data to CDC for detailed analysis, visualization, and surveillance, providing a national snapshot of the testing landscape and informing Federal response efforts. Section 18115 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act and HHS implementing guidance require all laboratories conducting testing for SARS-CoV–2 to report results to a State or local public health agency (which then report these data to CDC). The HHS implementing guidance allows for reporting using multiple potential methods, including ELR. All State PHAs are capable of and are receiving ELR for notifiable conditions.

We proposed at 86 FR 25637 to make the Electronic Reportable Laboratory Result Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022. We believe that making this measure required would spur hospital laboratories to adopt this capability, increase the timeliness and completeness of laboratory reporting to PHAs, strengthen the effectiveness of prevention and control measures, reduce the burden of reporting by laboratory staff, and aid in laboratory compliance with the requirements of section 18115 of the CARES Act as well as future PHEs. Requiring the Electronic Reportable Laboratory Result Reporting measure would incentivize the minority of hospital laboratories that have not adopted ELR to upgrade to this essential capability. With the availability of the APHL AIMS platform, HIEs, and other mechanisms, there is a diversity of options for eligible hospitals and CAHs to establish an ELR channel with a PHA to feasibly implement this requirement. In addition, CDC-provided ELR technical assistance is also available, further reducing implementation barriers.

We did not propose to change the description of the Electronic Reportable Laboratory Result Reporting measure and the exclusions that we established at 42 CFR 495.24(e)(8)(iii)(F) will remain available.

Comment: A commenter stated that during the COVID–19 pandemic, hospital clinical laboratories have cited problems collecting required data elements for reporting electronically to public health agencies. Electronic submission of laboratory results to public health agencies is not currently mandated at the Federal level, and states vary on whether electronic submission is required and on the format of the electronic submission. The commenter stated each interface with an EHR or with an individual state's public

health agency is costly ($40,000 to $70,000 on average per interface), and each change made to an interface also has associated cost. Further complicating the matter is the variability by state as to who is required to do the reporting, and the commenter indicated this will also need to be clarified if it is going to be standardized at a national level. To alleviate reporting burdens on clinical laboratories and state public health agencies, the commenter recommended national standardized reporting requirements and formats in which clinical laboratories would be required to report only to the state in which the laboratory is located, and the same national standards could be used by state public health agencies to report data on out-of-state patients to the state public health agency of the patient's residency. The commenter believes there is too much variability and obstacles in the current reporting structure to make this a required measure for 2022.

Response: We thank the commenter for their thoughts and we reiterate our position that making this measure required would spur hospital laboratories to adopt this capability, increase the timeliness and completeness of laboratory reporting to PHAs, strengthen the effectiveness of prevention and control measures, reduce the burden of reporting by laboratory staff, and aid in laboratory compliance with the requirements of section 18115 of the CARES Act as well as future PHEs. While we understand there are inconsistencies in reporting requirements depending on the jurisdiction, there are nearly 130 Modules certified to 170.315(f)(3) using HL7 2.5.1. Implementation specifications (HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)). CMS will continue to work with both the CDC and ONC to refine standards and address barriers to reporting, including ways to report once and redirect the information more seamlessly where needed.

After consideration of the public comments we received, we are finalizing our proposal to make the Electronic Reportable Laboratory Result Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022.

7. Scoring of the Public Health and Clinical Data Exchange Objective

We proposed that, beginning with the EHR reporting period in CY 2022, an eligible hospital or CAH would receive 10 points for the Public Health and Clinical Data Exchange objective if they report a ''yes'' response for each of the following 4 required measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting (86 FR 25638). In the event an eligible hospital or CAH is able to claim an exclusion for three or fewer of these four required measures, we proposed they would receive 10 points for the objective if they report a ''yes'' response for one or more of these measures and claim applicable exclusions for which they qualify for the remaining measures. If the eligible hospital or CAH fails to report on any one of the four measures required for this objective or reports a ''no'' response for one or more of these measures, we proposed that the eligible hospital or CAH would receive a score of zero for the Public Health and Clinical Data Exchange objective, and a total score of zero for the Medicare Promoting Interoperability Program. If an eligible hospital or CAH claims applicable exclusions for which they qualify for all four required measures, we proposed to redistribute the points associated with the objective to the Provider to Patient Exchange objective. We proposed corresponding changes to 42 CFR 495.24(e)(8)(ii) and (iii) to reflect these proposals.

We proposed to retain the Public Health Registry Reporting and Clinical Data Registry Reporting measures and to make them optional and available for bonus points beginning with the EHR reporting period in CY 2022. We proposed an eligible hospital or CAH may earn a maximum of 5 bonus points if they report a ''yes'' response for either the Public Health Registry Reporting measure OR the Clinical Data Registry Reporting measure. We proposed to further modify 42 CFR 495.24(e)(8)(ii) to add: Eligible hospitals and CAHs could receive a bonus of 5 points for this objective if they report the measures specified under 42 CFR 495.24(e)(8)(iii)(D) or (E).

In connection with our proposals to make these measures optional, we proposed the three exclusions that we established for each measure would no longer be available beginning with the EHR reporting period in 2022. For the Public Health Registry Reporting measure, we proposed to revise 42 CFR 495.24(e)(8)(iii)(D), and for the Clinical Data Registry Reporting measure we proposed to revise 42 CFR 495.24(e)(8)(iii)(E).

Comment: Many commenters supported our proposal to allocate five bonus points to eligible hospitals and CAHs that report either the Public Health Registry Reporting or the Clinical Data Registry Reporting measures.

Response: We appreciate the commenters support for this proposal.

Comment: A commenter recommended keeping the public health registry as one of the required registry measures, or, allowing the public health registry measure to be an option in the same category as the four proposed required registries (syndromic surveillance, immunization registry, electronic case reporting, and electronic reportable laboratory result). This will help rural and critical access hospitals meet requirements under the public health and clinical data exchange objective. While the commenter agreed with CMS on the critical importance of reporting to public health agencies to assist with responding to or preventing public health emergencies, the commenter is concerned the proposed approach will relegate clinical registry reporting to one of secondary importance. Hospitals have limited capacity to respond to the various government reporting requirements, and we fear some facilities may forego or drop optional reporting to clinical registries to meet these new public health reporting mandate. Clinical registries serve as the backbone for quality improvement in many medical specialties, and are critical to addressing the most common and high cost chronic conditions from which Medicare beneficiaries suffer, both during public health emergencies and normal times. As such, it is imperative that CMS ensure robust clinical registry reporting. As an alternative to CMS' proposal, the commenter recommended adding Clinical Data Registry Reporting measure to the four other types of required registry reporting measures, and drop the optional Public Health Registry Reporting measure since the key aspects of addressing any public health emergency are already covered through syndromic surveillance, electronic case reporting, electronic lab result reporting and immunizations.

Response: We do not agree that the public health registry and clinical data registry should be included in under the four required measures to be reported on. We considered the measures that were most likely to improve our readiness for future health threats. While we understand the concerns expressed by the commenters, we believe that awarding bonus points for the reporting of the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure will incentivize hospitals to

continue to submit data to these registries. Further we believe that once hospitals are actively reporting to clinical data registries that they will continue to do so even though it is not a requirement of the Medicare Promoting Interoperability Program. We will monitor hospitals' reporting of the four required measures to determine if we should modify the requirements in the future.

After consideration of the public comments we received, we are finalizing our proposals that beginning with the EHR reporting period in CY 2022, an eligible hospital or CAH would receive 10 points for the Public Health and Clinical Data Exchange objective if they report a ''yes'' response for each of the following 4 required measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting (86 FR 25638). Further, we are finalizing that in the event an eligible hospital or CAH is able to claim an exclusion for three or fewer of these four required measures, they would receive 10 points for the objective if they report a ''yes'' response for one or more of these measures and claim applicable exclusions for which they qualify for the remaining measures. If the eligible hospital or CAH fails to report on any one of the four measures required for this objective or reports a ''no'' response for one or more of these measures, we are finalizing that the eligible hospital or CAH would receive a score of zero for the Public Health and Clinical Data Exchange objective, and a total score of zero for the Medicare Promoting Interoperability Program. If an eligible hospital or CAH claims applicable exclusions for which they qualify for all four required measures, we are finalizing to redistribute the points associated with the objective to the Provider to Patient Exchange objective. We are modifying 42 CFR 495.24(e)(8)(ii) as proposed to add: Eligible hospitals and CAHs could receive a bonus of 5 points for this objective if they report the measures specified under 42 CFR 495.24(e)(8)(iii)(D) or (E). The three exclusions that we established for each measure will no longer be available beginning with the EHR reporting period in 2022. For the Public Health Registry Reporting measure, we are revising 42 CFR 495.24(e)(8)(iii)(D) as proposed, and for the Clinical Data Registry Reporting measure are revising 42 CFR 495.24(e)(8)(iii)(E), as proposed.

8. SAFER Guides

a. Background

ONC developed and released the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014, and later updated them in 2016. This series of nine user guides support hospitals' ability to address EHR safety.[1373] Collectively, the SAFER Guides help healthcare organizations to conduct self-assessments to optimize the safety and safe use of EHRs in the three areas listed in this rule, in Table IX.F.–01. The SAFER Guides were intended to be utilized by EHR users, developers, patient safety organizations, and those who are concerned with optimizing the safe use of Health IT. By completing a self-assessment using the SAFER Guides, providers can help to develop a ''culture of safety'' within their organizations and ensure they are responsible operators of technology tools, including certified health IT products, which they utilize in the delivery of care. The SAFER Guides are based on the best evidence available at the time of publication, including a literature review, expert opinion, and field-testing at a wide range of healthcare organizations, from small ambulatory care practices to large health systems.

In the FY 2019 IPPS/LTCH final rule (83 FR 41663), commenters expressed concern with having the ability to maintain continuous electronic connectivity, and identified a need to account for planned and unplanned system outages or downtime. In response, we referred readers to the SAFER Guides, to utilize and incorporate as a part of their emergency planning processes. In the case of system disruption, failure, or natural disaster, the SAFER Guides provide recommended safety practices during planned or unplanned EHR unavailability, where end users are unable to access all or part of their EHR. Also included are back-up procedures to prevent the potential loss of clinical and administrative data, and how to utilize paper charting during such downtime (83 FR 41663). We believe that conducting annual self-assessments based on the SAFER Guides' recommendations would satisfy stakeholder feedback received through the Annual Call for Measures and through public comment (83 FR 41663), supporting alternative and consistent safety practices for EHR users. We also believe requiring eligible hospitals and CAHs to conduct an annual self-assessment using the SAFER Guides would support the goals of improved EHR use and health care quality, as described in section 1886(n)(3)(A) of the Act.

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Table IX.F.-01. The SAFER Guides

Foundational Guides	- High Priority Practices - Organizational Responsibilities
Infrastructure Guides	- Contingency Planning - System Configuration - System Interfaces
Clinical Process Guides	- Patient Identification - Computerized Provider Order Entry with Decision Support - Test Results Reporting with Follow-Up - Clinician Communication

[1373] *https://www.healthit.gov/topic/safety/safer-guides.*

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b. New SAFER Guides Measure

We proposed in the FY 2022 IPPS/LTCH proposed rule (86 FR 25638), to add a new SAFER Guides measure to the Protect Patient Health Information objective beginning with the CY 2022 EHR reporting period. For this measure, we proposed that an eligible hospital or CAH must attest to having conducted an annual self-assessment of all nine SAFER Guides (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the EHR reporting period occurs, with one ''yes/no'' attestation statement accounting for a complete self-assessment using all nine guides. We proposed that in CY 2022, this measure would be required, but it would not be scored, and that reporting ''yes'' or ''no'' will not affect the total score for the Medicare Promoting Interoperability Program. We also proposed to add corresponding regulatory text for this measure at § 495.24(e)(4)(ii) and (iv).

In order to complete a ''self-assessment'' of the SAFER Guides we would expect that each eligible hospital or CAH would complete the checklist of recommended practices included at the beginning of each SAFER Guide. Following the checklist, a practice worksheet provides the rationale for, and examples of, how to implement each recommended practice, likely sources of input into the assessment of each practice, and fillable fields to record follow-up actions.

We understand that every organization faces unique circumstances, and will implement a particular safety practice differently. As a result, some of the specific examples in the SAFER Guides for recommended practices may not be applicable to every organization. We note that a ''self-assessment'' does not require an organization to confirm that it has implemented ''fully in all areas'' each practice described in a particular SAFER guide, nor will an organization be scored on how many of the practices the organization has fully implemented. Rather, the intent of this proposed requirement is for eligible hospitals and CAHs to regularly assess their progress and status on important facets of patient safety.

The recommended practices in the SAFER Guides are intended to be useful for all EHR users and, we recognize that the individuals responsible for the proposed annual self-assessment may vary across organizations. An optimal team for completing an annual review of the SAFER Guides might include representatives from an eligible hospital or CAHs clinical leadership, nursing staff, pharmacy representatives, and the staff responsible for implementing and maintaining both internal technology systems as well as data connections with external partners, such as an HIE.

Regarding the frequency of self-assessments using the SAFER Guides, we proposed that an eligible hospital or CAH must attest to completing their self-assessment using the SAFER Guides on an annual basis, following an initial completion of the self-assessment (some organizations may have already completed a self-assessment using the SAFER Guides prior to implementation of this requirement, if finalized). We would expect providers to revisit this assessment to determine whether any changes have occurred for their organization. We believe that requiring eligible hospitals and CAHs to periodically review this self-assessment as proposed would support a stronger culture of change management within organizations participating in the Medicare Promoting Interoperability Program, and would assist organizations in actively understanding and addressing potential safety vulnerabilities, which may significantly impact an organization's safety posture. We recognize that organizations may be at different stages in their progress towards assessing patient safety vulnerabilities and that hospitals vary in the resources that they could devote to annual self-assessment using the Guides. Gathering this information may be time consuming for small or rural hospitals that have contracted out some implementation services and may not have expertise available on staff to complete a full self-assessment using the SAFER Guides. For eligible hospitals and CAHs with less experience in these areas, we note that there are a number of resources available, which may be able to assist with completing a self-assessment.

We invited public comments on these proposals.

Comment: Many commenters supported our proposal to require a self-assessment, annually, of all nine SAFER Guides. Commenters stated that this requirement will encourage program participants to regularly assess their progress on practices that optimize the safety and safe use of EHRs, and others agree that completion of the self-assessments will promote best practices for the safe use and maintenance of health IT by hospitals.

Response: We would like to thank commenters for their support. We agree that given the opportunity to regularly assess progress, the SAFER Guides will help optimize the safety and safe use of EHRs, and allow eligible hospitals and CAHs the opportunity to make improvements as necessary over time.

Comment: Several commenters supported our proposal to require a self-assessment of all nine SAFER Guides, but have instead recommended an incremental approach to its implementation. Specifically, a commenter suggested that we allow eligible hospitals and CAHs three years to complete their self-assessment, rather than requiring an assessment of all nine guides annually. Another commenter suggested a phased-in approach, incrementally increasing the number of self-assessments that we would require annually.

Response: We appreciate the commenters' support. We believe that in requiring the completion of this self-assessment annually, it would assist organizations in actively understanding and addressing potential safety vulnerabilities regularly, which may significantly impact an organization's safety posture in a timelier manner. As discussed above, the ''self-assessment'' does not require an organization to confirm that it has implemented ''fully in all areas'' each practice, nor will the organization be scored on how many of the practices the organization has fully implemented. The intent is for eligible hospitals and CAHs to regularly assess their progress and status on important facets of patient safety. Last, as indicated in the following comment and response, initial assessments using the SAFER Guides may remain unaffected unless an eligible hospital made significant system upgrades or a transition between systems, and an eligible hospital or CAH could briefly review this existing self-assessment in order to complete the measure.

Comment: Several commenters supported of our proposal but have requested clarification and/or suggestions for improvement. A few commenters stated that many of the SAFER Guides represent one-time configuration or verification steps, which for many hospitals, would remain unchanged from year to year. These commenters further suggested that we clarify which guides hold a higher priority, so hospitals know how to better focus their efforts. A commenter suggested that CMS and ONC collaborate to ensure that the SAFER Guides be updated regularly to ensure the most current guidance is shared with eligible hospitals and CAHs. A commenter suggested that in lieu of requiring an annual self-assessment, ONC and CMS increase efforts for education and outreach, to

disseminate this information to hospitals. A couple commenters requested clarification that this requirement will not be scored, and that an answer of ''yes'' and ''no'' are both acceptable without affecting their total scores.

Response: We appreciate the commenters' support and suggestions. As discussed above, the completion of these self-assessments would assist organizations in actively understanding and addressing potential safety vulnerabilities regularly. The ''self-assessment'' does not require an organization to confirm that it has implemented ''fully in all areas'' each practice, nor will the organization be scored on how many of the practices the organization has fully implemented. As commenters have mentioned, several of the SAFER Guides will require an initial assessment that may not change significantly unless an eligible hospital made significant system upgrades or a transition between systems. Our larger focus is for eligible hospitals and CAHs to regularly assess their progress and status on important facets of patient safety. We would like to thank commenters for their suggestions that CMS and ONC coordinate efforts to regularly assess and update the SAFER Guides and to consider expanding on Education and Outreach efforts. We will continue to collaborate with ONC and take these suggestions under consideration. Last, we do confirm that for CY 2022, both ''yes'' and ''no'' are acceptable, an attestation of ''no'' will not alter final scores, and an attestation of ''no'' will not affect one's ability to be considered a Meaningful User.

Comment: Few commenters did not support our proposal to require a self-assessment of all nine SAFER Guides, annually. A commenter expressed concern that the SAFER Guides do not improve interoperability, but instead create additional reporting burden on hospitals. Another commenter stated that the SAFER Guides self-assessment would be out of scope for the Medicare Promoting Interoperability Program. A commenter stated that due to the reporting burden this requirement may cause, if we should finalize, we should consider postponing until the CY 2023 reporting period at a minimum.

Response: We want to thank these commenters for sharing their feedback and concerns. With a central focus on patient safety, we disagree that the SAFER Guides self-assessments are out of scope for the Medicare Promoting Interoperability Program. We would like to remind commenters that the Protect Patient Health Information objective is essential to all aspects of Meaningful Use, and ensuring that Patient Health Information is protected and secure assists in addressing the unique risks and challenges that EHRs may present. Under the Protect Patient Health Information objective, the SAFER Guides measure is one way that we can proactively assess individual readiness. Therefore, we respectfully disagree that the SAFER Guides self-assessment is out of scope for our Program. For the commenter who raised concerns about the additional reporting burdens this measure may present, we appreciate this feedback. We would like to reiterate that eligible hospitals and CAHs are not being scored on this measure, that an attestation of ''yes'' and ''no'' are both acceptable answers without penalty, and that eligible hospitals and CAHs will vary in their levels of implementation. Last, after an initial self-assessment, several of the SAFER Guides will not require the same type of annual assessments, absent vendor and/or system changes.

After consideration of the public comments we received, we are finalizing our proposal to add a new SAFER Guides measure to the Protect Patient Health Information objective beginning with the CY 2022 EHR reporting period. Eligible hospitals or CAHs must attest to having conducted an annual self-assessment of all nine SAFER Guides (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the EHR reporting period occurs, with one ''yes/no'' attestation statement accounting for a complete self-assessment using all nine guides. We are finalizing that in CY 2022, this measure will be required, eligible hospitals and CAHs are not being scored on this measure, and that an attestation of ''yes'' and ''no'' are both acceptable answers without penalty. We are also finalizing our proposal to add corresponding regulatory text for this measure at § 495.24(e)(4)(ii) and (iv).

9. Actions To Limit or Restrict the Compatibility or Interoperability of CEHRT

a. Background

Section 106(b)(2) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) includes the heading ''Preventing Blocking The Sharing Of Information.'' Section 106(b)(2)(B) amended section 1886(n)(3)(A)(ii) of the Act for eligible hospitals and, by extension, section 1814(l)(3) of the Act for CAHs to require that a hospital demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the hospital has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology. To implement these provisions, we established and codified at 42 CFR 495.40(b)(2)(i)(I) attestation requirements for the Promoting Interoperability Programs to support the ''prevention of information blocking,'' which consist of three statements containing specific representations about a health care provider's implementation and use of CEHRT. For further discussion on these requirements, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77028 through 77035) and the Interoperability and patient access final rule (85 FR 25578 through 25580). The attestation statements finalized for eligible hospitals and CAHs at 42 CFR 495.40(b)(2)(i)(I) are:

- *Statement 1:* Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.
- *Statement 2:* Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and vendors.
- *Statement 3:* Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

Participants in the Medicare Promoting Interoperability Program that are required to attest to the three statements under 42 CFR 495.40(b)(2)(i)(I) are also subject to public reporting as established in the Patient Access and Interoperability final rule (85 FR 25578 through 25580).

Under this policy, we will post information on a CMS website available to the public for eligible hospitals and CAHs who have attested ''no'' to any of these three statements. Section 4004 of the 21st Century Cures Act added section 3022 to the Public Health Service Act (PHSA) (the ''PHSA information blocking provision''), which describes practices by health care providers, health IT developers, and health information exchanges and networks, that constitute information blocking, and provides for civil monetary penalties and other disincentives for those who engage in information blocking. In the ONC 21st Century Cures Act final rule published in the **Federal Register** on May 1, 2020, ONC finalized a definition of information blocking and identified reasonable and necessary activities (''exceptions'') that do not constitute information blocking (85 FR 25642). For health care providers (as defined in 42 U.S.C. 300jj) ''information blocking means a practice that (1) Except as required by law or covered by an exception [. . .], is likely to interfere with access, exchange, or use of electronic health information; and if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information'' (45 CFR 171.103).

The Cures Act provides for civil monetary penalties for any individual or entity that is a developer, network, or exchange that has committed information blocking (see section 3022(b)(2)(A) of the PHSA). Regarding health care providers, the Cures Act provides that ''Any [health care provider] determined by the [HHS] Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking'' (section 3022(b)(2)(B) of the PHSA). For more information about the information blocking policies finalized in the ONC 21st Century Cures Act final rule, see *https://www.healthit.gov/curesrule/final-rule-policy/information-blocking*.

b. Changes to the Attestation Statements

Although there could be some degree of overlap between conduct described in the attestation statements under 42 CFR 495.40(b)(2)(i)(I) and conduct that could be considered information blocking under section 3022 of the PHSA and ONC's implementing regulations at 45 CFR 171.103, it is important to note these are separate and distinct authorities. For instance, the ONC 21st Century Cures Act final rule finalized a definition for what constitutes information blocking, and exceptions to information blocking that are not reflected in the previously finalized attestation statements under 42 CFR 495.40(b)(2)(i)(I). While we previously stated in the 2017 QPP final rule that these attestations statements did not impose ''unnecessary or unreasonable requirements'' on health care providers (81 FR 77029), after careful review of these statements in light of the information blocking regulations at 45 CFR part 171, we believe that statements 2 and 3 are no longer necessary. Thus, beginning with the CY 2022 EHR reporting period, we proposed at 42 CFR 495.40(b)(2)(i)(I) and (J) to no longer require statements 2 and 3. We believe that the similarities between practices described under statements 2 and 3, and the practices that could constitute information blocking under section 3022 of the PHSA and ONC's implementing regulations will create confusion for stakeholders. To this point, the practices that could constitute information blocking under 45 CFR part 171 are much broader than those described in the attestation statements. We discuss specific instances of potential confusion in this final rule.

Statement 2 requires attestation to a series of statements regarding the use of certified technology and a designated manner for implementing certified technology. For instance, attestations to the implementation of technology compliant with the standards for certified health IT at 45 CFR part 170, and use of functionality to support health information exchange with other providers. However, as previously stated, the definition of information blocking finalized in the ONC 21st Century Cures Act final rule is not specific to, nor limited to, the use of certified technology which is compliant with certain standards or the use of certain functionality. Under the ONC 21st Century Cures Act final rule, a health care provider may still be determined to have engaged in practices likely to interfere with access, exchange, or use of electronic health information (information blocking) regardless of whether they are using certified technology.

Regarding statement 3, we stated in the 2017 QPP final rule that ''technical, legal, and other practical constraints may prevent a health care provider from responding to some requests to access, exchange, or use electronic health information in a health care provider's certified EHR technology'' (81 FR 77033). Subsequently, in the ONC 21st Century Cures Act final rule, ONC established a set of reasonable and necessary activities that are not considered information blocking when responding to a request for EHI. The reasonable and necessary activities established under the ONC 21st Century Cures Act final rule now provide more specific direction to providers when responding to a request for EHI than the general ''technical, legal, and other practical constraints'' which we described in the QPP 2017 final rule with regards to statement 3. Accordingly, we believe that continuing to require statement 3 may introduce confusion for those health care providers who are obligated to comply with the regulations finalized in the ONC 21st Century Cures Act final rule when responding to a request for EHI.

In order to distinguish the attestation required by section 106(b)(2)(B) of MACRA from information blocking under section 3022 of the PHSA, we proposed in the FY 2022 IPPS/LTCH proposed rule (86 FR 25639 through 25641), to modify the heading of the regulation text at 42 CFR 495.40(b)(2)(i)(I) and the definition of ''meaningful EHR user'' under 495.4 from ''Support for health information exchange and the prevention of information blocking'' to ''Actions to limit or restrict the compatibility or interoperability of CEHRT,'' which reflects the language used in section 106(b)(2)(B) of MACRA.

We invited public comments on our proposals.

Comment: All commenters expressed support for our proposal to no longer require Statements 2 and 3 under 42 CFR 495.40(b)(2)(i)(I). Commenters shared appreciation for our efforts to eliminate duplicative reporting burden, eliminate redundancies, and our efforts towards streamlining our requirements.

Response: We thank commenters for their support and positive feedback. We are continuing to make efforts towards alignment across programs and agencies, and reducing reporting burden among eligible hospitals and CAHs.

After consideration of the public comments, we are finalizing our proposal without modification. That is, we will no longer require Statements 2 and 3 under 42 CFR 495.40(b)(2)(i)(I) and (J), beginning with the EHR reporting period in 2022. Additionally, we are finalizing our proposal to modify the heading of the regulation text at 42 CFR 495.40(b)(2)(i)(I), and the definition of ''meaningful EHR user'' under 495.4 from ''Support for health information exchange and the prevention of information blocking'' to ''Actions to

limit or restrict the compatibility or interoperability of CEHRT.''

10. Overview of Objectives and Measures for the Medicare Promoting Interoperability Program in 2022

For ease of reference, Table IX.F.–02 lists the objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2022 as revised to reflect the final policies established in this final rule. Table IX.F.–03 lists the 2015 Edition certification criteria required to meet the objectives and measures.

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TABLE IX.F.-02: Objectives and Measures for the Medicare Promoting Interoperability Program in 2022

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing	e-Prescribing: For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using certified electronic health record technology (CEHRT).	The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically.	The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their electronic health record (EHR) reporting period.
Electronic Prescribing	Query of Prescription Drug Monitoring Program (PDMP) (bonus): For at least one Schedule II opioid electronically prescribed using certified electronic health record technology (CEHRT) during the electronic health record (EHR) reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the	Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and	Number of transitions of care and referrals during the electronic health record (EHR) reporting period for which the	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using certified electronic health record technology (CEHRT); and (2) electronically exchanges the summary of care record.	exchanged electronically.	eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transitioning or referring provider.	
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received for patient encounters during the electronic health record (EHR) reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication Allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using certified electronic health record technology (CEHRT) for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	reconciliation for medication, medication allergy, and current problem list.			
Health Information Exchange	Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE) (Alternative to two previous HIE measure)	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and the eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical	The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the eligible hospitals or CAH's CEHRT.	The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	specifications of the application programming interfaces (API) in the eligible hospital or CAHs certified electronic health record technology (CEHRT).			
Public Health and Clinical Data Exchange	Immunization Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the eligible hospital or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or IIS during the electronic health record (EHR) reporting period; (2) Operates in a jurisdiction for which no immunization registry or IIS is capable of accepting the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no immunization registry or IIS has declared readiness to receive immunization data as of six months prior to the start of the EHR reporting period.
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an emergency department.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency department; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the

Objective	Measure	Numerator	Denominator	Exclusion
				specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the electronic health record (EHR) reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of six months prior to the start of the EHR reporting period.
Public Health and Clinical Data Exchange	Electronic Case Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit case reporting of reportable conditions.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the electronic health record (EHR) reporting period; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHS has declared readiness to receive electronic case reporting data as of six months prior to the start of the EHR reporting period.
Public Health and Clinical Data Exchange	Electronic Reportable Laboratory (ELR) Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit ELR results.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in their jurisdiction during the electronic health record (EHR) reporting period;

Objective	Measure	Numerator	Denominator	Exclusion
				(2) Operates in a jurisdiction for which no PHA is capable of accepting the specific ELR standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive ELR results from an eligible hospital or CAH as of six months prior to the start of the EHR reporting period.
Public Health and Clinical Data Exchange	Public Health Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit data to public health registries.	N/A (measure is Y/N)	N/A (measure is Y/N)	none
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: The eligible hospital or CAH is in active engagement to submit data to a clinical data registry (CDR).	N/A (measure is Y/N)	N/A (measure is Y/N)	none
Protect Patient Health Information	Security Risk Assessment	N/A (measure is Y/N)	N/A (measure is Y/N)	none
Protect Patient Health Information	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	N/A (measure is Y/N)	N/A (measure is Y/N))	none

TABLE IX.F.-03: Medicare Promoting Interoperability Program Objectives and Measures, and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Bonus: Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE) Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria: § 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting

Public Health and Clinical Data Exchange		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Electronic reportable laboratory result reporting	§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
Electronic Clinical Quality Measures (eCQMs)	eCQMs for eligible hospitals and CAHs	§ 170.315(c)(1) § 170.315(c)(2) § 170.315(c)(3)(i) and (ii) § 170.315(c)(4) (optional)
Protect Patient Health Information	Security Risk Assessment	§ 164.308 (a)(1)
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	The requirements are a part of CEHRT specific to each certification criterion.[1]

[1]Technical update from FY 2022 IPPS/LTCH PPS proposed rule

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10. Proposed Changes to the Scoring Methodology for the EHR Reporting Period in CY 2022

a. Proposed Performance-Based Scoring Threshold Increase

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41645), we adopted a new performance-based scoring methodology for eligible hospitals and CAHs attesting under the Medicare Promoting Interoperability Program which included a minimum scoring threshold which eligible hospitals and CAHs must meet in order to satisfy the requirement to report on the objectives and measures of meaningful use under 42 CFR 495.24. We established at 42 CFR 495.24(e)(1)(i) that eligible hospitals and CAHs must earn a total score of at least 50 points on the objectives and measures to be considered a meaningful EHR user.

The Medicare Promoting Interoperability Program's performance results from CY 2019 (the first full year of programmatic data demonstrating the new performance-based scoring methodology) revealed that 3,776 of 3,828 participating eligible hospitals and CAHs that reported to the program successfully met the minimum threshold score of 50 points.

For CY 2022 and subsequent years, we proposed in the FY 2022 IPPS/LTCH proposed rule (86 FR 25649) to increase the minimum scoring threshold from 50 points to 60 points, and proposed corresponding changes to the regulation text at 42 CFR 495.24(e)(1)(i)(C). Given the widespread success of participating hospitals in CY 2019, we believe that such program results signify the need for raising the minimum score for CY 2022. We note that eligible hospitals and CAHs will have gained two more years of experience in the Medicare Promoting Interoperability Program (CYs 2020 and 2021) at the 50-point minimum score threshold to improve performance. This increase from 50 points to 60 points represents our intent to heighten the required standards for the Medicare Promoting Interoperability Program's performance levels and encourage higher levels of performance through the advanced usage of CEHRT in order to further incentivize eligible hospitals and CAHs to improve interoperability and health information exchange.

We sought comments on our proposal to increase the minimum scoring threshold from 50 to 60 points.

Comment: Generally, commenters supported our proposal for CY 2022 and subsequent years to increase the minimum scoring threshold from 50 to 60 points. Some commenters cited that the increase was of a reasonable amount and that the Medicare Promoting Interoperability Program's threshold had remained unchanged for several years, stating that the proposed increase to 60 points would be an opportunity to show continued growth in the program and reflect the success of its participants.

Response: We thank the commenters for their support and agree that, based upon the success of the program, it is appropriate to increase the minimum scoring threshold. Data results from program year 2019 showed that 98.6% of participating hospitals scored higher than the current 50 point minimum. As the 50-point threshold has been in place since CY 2019, we continue to believe that the program is prepared to adapt and evolve toward this increased standard of participation for consideration as a meaningful EHR user. We've stated that eligible hospitals and CAHs would have gained two additional years of experience in the program (CYs 2020 and 2021) with the current threshold of 50 points, and this increase to 60 points represents our desire to encourage higher levels of program performance and to further incentivize eligible hospitals and CAHs to improve their advancement toward interoperability, promote greater health information exchange, and raise overall patient care quality.

Comment: Some commenters, while agreeing in theory with a proposed increase to 60 points, indicated their desire to stress the importance of CMS taking a measured and staged approach in any future program changes (including adjustments made to the minimum scoring threshold). Several commenters expressed concerns over whether smaller, rural, or emerging hospitals would struggle to meet the 60-point threshold and fail to qualify as meaningful EHR users. The same commenters also highlighted the Public Health Emergency surrounding COVID–19 as a challenging time to improve overall performance for those eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

Response: We thank the commenters for sharing their concerns surrounding the proposed rule's change to increase the program's minimum scoring threshold. While we admit to widespread difficulties experienced by eligible hospitals and CAHs during the Public Health Emergency, we believe that there has been sufficient time since CY 2019 for programmatic stability in

the Medicare Promoting Interoperability Program's available objectives and measures to warrant such a nominal increase of 10 points. We would like to highlight that this final rule includes several finalized changes in the Medicare Promoting Interoperability Program which allow expanded opportunities for additional bonus points as well as new measure options that we believe could grant the necessary points to achieve more than the required 60-point scoring threshold. As other submitted commenters cited, we've balanced this increase against the full scope of the Medicare Promoting Interoperability Program changes which considers the role of bonus points in meeting or surpassing the minimum threshold. Specifically, we'd point to the inclusion of finalized changes surrounding 10 bonus points in the Query of PDMP measure, an additional 5 bonus points in the Public Health and Clinical Data Exchange objective, as well as a new alternative Health Information Exchange Bi-Directional Exchange measure. Combined, we believe that these finalized efforts would offer more than sufficient opportunity for eligible hospitals and CAHs to offset an increase to the Medicare Promoting Interoperability Program's minimum scoring threshold, therefore negating any need to delay the increase to a future calendar year.

After consideration of the public comments we received, we are finalizing our proposals without modification. That is, for CY 2022 and subsequent years, we are increasing the minimum scoring threshold from 50 points to 60 points. We are also finalizing, as proposed, the corresponding changes to the regulation text at 42 CFR 495.24(e)(1)(i)(C).

b. Performance-Based Scoring Methodology Table Updates

The following table reflects the objectives and measures as finalized for CY 2022. As discussed in section IX.F.3.c of this final rule, we are finalizing our proposals for CY 2022 to include the optional Query of PDMP measure worth 10 bonus points, the adoption of a new alternative Health Information Exchange Bi-Directional Exchange measure, the adoption of a SAFER Guides measure, and modified requirements for the Public Health and Clinical Data Exchange objective.

Table IX.F.-04: Performance-Based Scoring Methodology

EHR Reporting Period in CY 2022

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)*
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
	-OR-	
	Health Information Exchange Bi-Directional Exchange*	40 points*
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report the following 4 measures:* • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting	10 points
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (*bonus*)*

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.

*Signifies a final policy adopted in this FY 2022 IPPS/LTCH final rule.

11. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Changes to Clinical Quality Measures in Alignment With the Hospital IQR Program

(1) Background

Under sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures (referred to as CQMs or eCQMs) selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare Promoting Interoperability Program.

The following table lists previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare Promoting Interoperability Program (84 FR 42597 through 42599) for the reporting period in CY 2021 and in subsequent years. The table includes the Safe Use of Opioids—Concurrent Prescribing measure (NQF #3316e) which we finalized as mandatory for reporting beginning with CY 2022 (84 FR 42598 through 42600).

Table IX.F.-05: CQMs for Eligible Hospitals and CAHs for CY 2021 and Subsequent Years

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

(2) eCQM Removals

As we discuss in the Hospital IQR Program section of this final rule, we proposed to remove four eCQMs from the Hospital IQR Program's measure set effective for the CY 2024 reporting period/FY 2026 payment determination in the FY 2022 IPPS/LTCH proposed rule (86 FR 25650). Specifically, we proposed to remove:

- STK–03 (Anticoagulation Therapy for Atrial Fibrillation/Flutter),
- STK–06 (Discharged on Statin Medication),
- PC–05 (Exclusive Breast Milk Feeding), and
- ED–2 (Admit Decision Time to ED Departure Time for Admitted Patients).

We refer readers to section IX.C. of the preamble of this final rule for additional discussion of the rationales for these removals from the Hospital IQR Program.

We continue to believe that aligning the CQM requirements that we adopt in the Medicare Promoting Interoperability Program with the Hospital IQR Program's eCQM requirements benefits hospitals that are working to comply with each program's requirements. Aligning the requirements and measure sets across programs promotes efficiency and harmonizes with our goal of applying a parsimonious set of the most meaningful measures available to track patient outcomes and impact. We believe that maintaining alignment between the Hospital IQR Program and the Medicare Promoting Interoperability Program streamlines our approach to data collection, calculation, and reporting using EHRs. We further believe that this streamlined approach allows us to leverage clinical and patient-centered information for measurement, improvement, and learning.

To maintain this alignment between the Hospital IQR Program and Medicare Promoting Interoperability Program, and for the reasons described in section IX.C. of the preamble to this final rule, we are removing STK–06, PC–05, and ED–2 from the previously finalized set of eCQMs for the Medicare Promoting Interoperability Program beginning with the reporting period in CY 2024.

We welcomed public comments on the proposed eCQM removals.

Comment: Many commenters generally supported our proposal to remove STK–03. Several commenters supported our proposal to remove STK–03 because removing the measure reduces administrative burden, and agree that the costs associated with the measure outweigh the benefits of retaining it in the Medicare Promoting Interoperability Program. A commenter supported our proposal to remove STK–03 because the removal will add balance to the core set of eCQMs available for reporting.

Response: We thank the commenters for their support of our proposal to remove STK–03, and agree with commenters that, the costs associated with the measure outweigh the benefits of retaining it. Therefore, we are not finalizing our proposal, as is detailed below.

Comment: A number of commenters did not support our proposal to remove

STK–03. Commenters asserted their belief that the STK–02 measure does not specifically target prescribing of anticoagulation therapy to patients at discharge. Commenters identified that ischemic stroke patients are not all the same, noting their belief that patients with non-cardioembolic ischemic stroke should be treated with antiplatelet medication, rather than anticoagulation. Commenters also pointed out the distinction that the STK–03 eCQM makes between the general category of antithrombotic therapy and the specific subset of anticoagulant therapy, whereas STK–02 does not ensure that stroke patients with atrial fibrillation are appropriately prescribed an anticoagulant as guidelines recommend. Commenters expressed their belief that anticoagulation has historically been dramatically underutilized for stroke prevention in patients with atrial fibrillation, such that prescribing it at discharge is an important opportunity to improve appropriate use in these patients. Commenters were concerned that removing STK–03 could result in fewer stroke patients receiving appropriate anticoagulant therapy.

Response: We appreciate commenters' concerns. We have confidence that hospitals are committed to providing good quality care to stroke patients and we do not have any indication that they will stop doing so in these areas for which the quality of care has become standard practice. After considering stakeholder concerns, we plan to retain the STK–03 eCQM in the Medicare Promoting Interoperability Program's measure set and are thus not finalizing the removal in this final rule.

Comment: A commenter did not support our proposal to remove STK–03 because of their belief that this removal would magnify racial inequities in prescription and treatment that non-white stroke patients face.

Response: We appreciate the commenter's concern related to racial disparities. As stated earlier we are focused on and committed to closing the health equity gap as seen in the Health Equity RFI (86 FR 25554 through 25561). We wish to clarify that STK–03 is not stratified by race which limits the ability of the measure to directly capture or address racial disparities. We note that after consideration of stakeholder concerns, we are not finalizing our proposal to remove this measure.

Comment: Several commenters did not support our proposal to remove STK–03 because they believed that removing it would decrease the number of available eCQMs for hospitals to choose from and discounts the investment of resources hospitals must expend to operationalize an eCQM.

Response: We are finalizing our proposal to adopt two additional eCQMs and refer readers to sections IX.C.5.d.1. and IX.C.5.d.2. for more detail on our finalized proposals to adopt the Hospital Harm-Severe Hypoglycemia eCQM and Hospital Harm—Severe Hyperglycemia eCQM. We note that after consideration of stakeholder concerns, we are not finalizing our proposal to remove this measure. We reiterate that we intend to introduce additional eCQMs into the program as ones that support out evolving program goals become available.

Comment: Many commenters expressed support for our proposal to remove the STK–06 eCQM from Medicare Promoting Interoperability measure set. Several stated the proposal would reduce unnecessary administrative and reporting burden and expressed appreciation for CMS' efforts to continually review the measure set and balance the core set of eCQMs reported to CMS.

Response: We thank commenters for their support of the proposal to remove STK–06 from the Medicare Promoting Interoperability Program.

Comment: A few commenters did not support our proposal to remove the STK–06 measure due to concern that small hospitals lack other eCQMs to report based upon their patient population. A commenter did not support our proposal due to the investment of time and resources previously incurred to implement the measure.

Response: We acknowledge that facilitating quality improvement for small hospitals can present unique challenges. We understand the concern that the ability to submit zero denominator exemption does not provide direct information for supporting quality improvement efforts. It remains our goal to expand EHR-based quality reporting in the Medicare Promoting Interoperability program which we believe will ultimately provide more flexibility for hospitals to choose the measures that are most representative of their patient populations. We also acknowledge the time, effort and resources that hospitals expend on implementing eCQMs. However, we believe that measure removal will be less burdensome to hospitals overall than continuing to retain a measure in the Medicare Promoting Interoperability Program. As part of the Meaningful Measures Initiative to include a parsimonious set of the most meaningful measures for patients and clinicians in our quality programs to reduce burden, cost and program complexity, our decision to remove measures from the Medicare Promoting Interoperability Program is an extension of our programmatic goal to continually refine the measure set (83 FR 41574).

Comment: Many commenters supported our proposal to remove the ED–2 eCQM. Some commenters appreciated that the removal would reduce burden on hospitals and others agreed that the costs associated with ED–2 outweigh the benefit of its continued use in the Medicare Promoting Interoperability Program. A few commenters questioned whether boarding times accurately reflect quality of care and some suggested that quality of care is more impacted by external factors such as access to behavioral health treatment, patterns of primary care deliver, and nursing shortages.

Response: We thank the commenters for the support of our proposal to remove the ED–2 eCQM. While we continue to believe that prolonged emergency department board times is an important issue, we agree that the Admit Decision Time to ED Departure Time for Admitted Patients has had inconclusive associations with adverse outcomes such as in-hospital mortality and the quality of care in the inpatient setting. We understand that other factors, in addition to boarding times, impact outcomes and note that this measure was not intended to suggest otherwise. We note that we will continue measuring ED boarding times in the outpatient setting via measure OP–18, Median Time from ED Arrival to ED Departure for Discharged ED Patients, in the Outpatient Quality Reporting Program. We appreciate the commenters' feedback and will take it into consideration as we continually refine the measure sets for our quality programs.

After consideration of the public comments we received, we are not finalizing our proposal to remove the Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03) eCQM. We thank the commenters for their comments and suggestions, which we will take into consideration when assessing what changes, if any, should be incorporated into this important measure for the future. However, after consideration of the public comments we received, we are finalizing our proposal to remove STK–06 (Discharged on Statin Medication), PC–05 (Exclusive Breast Milk Feeding), and ED–2 (Admit Decision Time to ED Departure Time for Admitted Patients) from the previously finalized set of eCQMs for the Medicare Promoting Interoperability Program

beginning with the CY 2024 reporting period.

(3) eCQM Adoptions

As we have stated previously in rulemaking (82 FR 38479), we plan to continue to align the CQM reporting requirements for the Promoting Interoperability Program with similar requirements under the Hospital IQR Program. Further, as we discuss in section IX.C. of the preamble of this final rule, we are adopting two new eCQMs in the Hospital IQR Program beginning with the CY 2023 reporting period/FY 2025 payment determination:

- Hospital Harm—Severe Hypoglycemia (NQF #3503e), and
- Hospital Harm—Severe Hyperglycemia (NQF #3533e).

We refer readers to section IX.C. of the preamble of this final rule for additional discussion of the technical details associated with these measures, their data sources, calculations, cohorts, and risk adjustment.

As previously discussed, with respect to eCQM removals, we continue to believe that adopting aligned requirements between the Hospital IQR and Medicare Promoting Interoperability Program is beneficial to participating hospitals. To maintain this alignment and to support hospitals' ability to choose amongst a consistent pool of CQMs, as well as the clinical importance of these measures as discussed in section IX.C. of the preamble to this final rule, in the FY 2022 IPPS/LTCH proposed rule (86 FR 25650 through 25651) we proposed to adopt the Severe Hypoglycemia and Severe Hyperglycemia CQMs for the Medicare Promoting Interoperability Program beginning with the reporting period in CY 2023.

We welcomed public comments on the proposed eCQM adoptions.

Comment: Many commenters expressed support for the inclusion of the Hospital Harm—Severe Hyperglycemia eCQM into the Medicare Promoting Interoperability Program measure set. Commenters stated their belief that the measure will increase transparency, drive improvements in care, and improve patient outcomes. A commenter appreciated that this measure can be applied broadly to various sized hospitals and another commenter highlighted that this measure will expand the number of eCQMs available to rural and specialty hospitals for quality reporting. A commenter stated that this measure is in alignment with the goals put forth in the National Action Plan for Adverse Drug Event Prevention (Action Plan). Commenters supported adoption of the measure and appreciated our commitment to align eCQMs in the Medicare Promoting Interoperability Program with the Hospital IQR Program.

Response: We thank commenters for their support and input. We agree that this measure, which captures important quality information that is critical to patient safety and improving patient outcomes, should be included in the Medicare Promoting Interoperability Program measure set.

Comment: Many commenters provided feedback on the implementation timeline for the measure. A few commenters agreed that the CY 2023 reporting period is a reasonable and appropriate timeline for a new measure, while several commenters believed that the measure should be delayed. A commenter requested an 18-month delay, while others requested one additional year, recommending inclusion beginning with the CY 2024 reporting period.

Response: We thank the commenters for their support and input. We note that this measure was proposed for inclusion beginning in the CY 2023 reporting period, which would allow hospitals at least one full year to implement. We appreciate commenters' requests for an 18 to 24-month delay, but respectfully disagree that reporting in CY 2023 is unreasonable. We direct readers to the eCQI Resource Center (available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*) for the draft specifications for this eCQM, several other eCQMs being finalized, as well as those we sought comment on in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070).

Comment: Several commenters shared feedback on the adoption of Hospital Harm—Severe Hypoglycemia as a balancing measure to Hospital Harm—Severe Hyperglycemia. A few stated their support for both measures, recommending that we allow hospitals to choose which of the two measures to report. A commenter recommended CMS require reporting of both eCQMs. A commenter recommended that we require hospitals to report on the Hospital Harm—Severe Hypoglycemia measure, while a few others preferred that reporting on it be kept optional. A few commenters stated that they could not support the adoption of these balancing measures as they believed they were not aligned. A commenter had concerns about complexity of the Hospital Harm—Severe Hypoglycemia measure.

Response: We thank commenters for their feedback. Hospitals will be able to report the Severe Hyperglycemia and Severe Hypoglycemia measures independently. Balancing measures are measures that can be used to demonstrate that an improvement in one area is not negatively impacting improvement in another area. For example, we can use these measures to assess whether an improvement in the number of severe hyperglycemia events ties to an increase in the number of severe hypoglycemia events. For that reason, while the two measures may not measure the same exact thing, we consider them to be balancing measures. We believe that both measures, regardless of the denominator used, will trend downward as improvements are made. Additionally, we note that hospitals may self-select to report on one, both, or none of these two finalized eCQMs. As finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58970 through 58975), hospitals are required to report on: (a) Three self-selected eCQMs and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (Safe Use eCQM), for a total of four eCQMs.

Comment: Many commenters supported adopting the Hospital Harm—Severe Hypoglycemia eCQM in the Medicare Promoting Interoperability Program. Commenters expressed their belief that the measure will improve both transparency and patient outcomes. A commenter highlighted that the measure can be easily implemented. A few commenters support the inclusion of the measure and emphasized the importance of glycemic control for reducing patient harm.

Response: We thank commenters for their support of and input on the inclusion of Hospital Harm—Severe Hypoglycemia (NQF #3503e) in the Medicare Promoting Interoperability Program measure set beginning with the CY 2023 reporting period. We agree that this measure captures important quality information that is critical to patient safety and improving patient outcomes.

Comment: A few commenters did not support the inclusion of Hospital Harm—Severe Hypoglycemia into the Medicare Promoting Interoperability Program measure set due to testing. These commenters expressed concern about the level of testing, requesting that the measure undergo additional testing for feasibility and validity prior to finalization. Another commenter expressed support for the measure, but also requested we conduct additional testing.

Response: We thank the commenters for their input and feedback on this measure. We understand the value of sample size in measure testing, and note that measure testing was done in

compliance with the NQF requirements for eCQM development. The Hospital Harm—Severe Hypoglycemia eCQM was tested in 6 hospitals representing two EHR systems that provided a good representation of hospitals across the country. This aligns with NQF's recommendation to conduct eCQM testing in more than one EHR system. Empirical results also showed that the measure exhibited high feasibility, reliability, and data element validity. The thresholds were found to be feasible, reliable, valid, and scientifically acceptable by the NQF Patient Safety Standing Committee and the measure was endorsed by the NQF Consensus Standards Advisory Committee (CSAC) in the Spring of 2019.

Comment: Several commenters supported the Hospital Harm—Severe Hypoglycemia measure, but requested CMS delay the inclusion of the eCQM to allow additional time for hospitals to implement the measure. A commenter requested an 18-month delay, while others requested one additional year, recommending inclusion beginning with the CY 2024 reporting period. A few commenters requested additional time to pilot the measure before formally adopting it into the Medicare Promoting Interoperability Program.

Response: We thank commenters for their support and input. We emphasize that the Hospital Harm—Severe Hypoglycemia measure was proposed for inclusion beginning in the CY 2023 reporting period, which would allow hospitals at least one full year to implement. We appreciate commenters' requests for an 18 to 24-month delay, but respectfully disagree that reporting in CY 2023 is unreasonable. We direct readers to the eCQI Resource Center (available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*) for the draft specifications for this eCQM, several other eCQMs being finalized, as well as those we sought comment on in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070). We thank commenters for the suggestion to allow additional pilot time, but feel that a CY 2023 implementation will allow eligible hospitals and CAHs the time necessary to complete testing activities.

Comment: A commenter recommended that we provide sufficient guidance on the time windows for ''day'' as it relates to the proposed Hospital Harm—Severe Hypoglycemia measure's definition and specification description. They noted that the measure could use clarification on how hospitals would calculate or count the length of a ''day'', such as whether it constitutes a calendar day or 24-hour day (as clocked from the first point of patient documentation).

Response: We thank the commenter for their feedback. We note that the Hospital Harm—Severe Hypoglycemia eCQM specifies the time window as 24 hours. For more detailed information and measure guidance, we refer readers to the draft specifications for this measure, available on the eCQI Resource Center (available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*). After consideration of the public comments we received, we are finalizing the inclusion of Hospital Harm—Severe Hypoglycemia eCQM (NQF #3503e) and Hospital Harm—Severe Hyperglycemia eCQM (NQF#3533e) to the Medicare Promoting Interoperability Program measure set, in alignment with similar proposals also finalized by the Hospital IQR Program, beginning with the CY 2023 reporting period. We thank the public for their input and support.

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Table IX.F.-06: CQMs for Eligible Hospitals and CAHs for CY 2022

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

Table IX.F.-07: CQMs for Eligible Hospitals and CAHs for CY 2023

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

Table IX.F.-08: CQMs for Eligible Hospitals and CAHs for CY 2024 and Subsequent Years

Short Name	Measure Name	NQF No.
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

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(4) Updates to Certification Requirements for eCQM Reporting—2015 Edition Cures Update

In the ONC 21st Century Cures Act final rule, ONC revised the clinical quality measurement criterion at § 170.315(c)(3) to refer to CMS QRDA Implementation Guides and remove the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25686). The § 170.315(c)(3) revision was responsive to industry feedback that the health IT certified to the prior ''CQMs-report'' criterion was only primarily being used to submit eCQMs for CMS reporting programs. This update was finalized to reduce burden on health IT developers under the ONC Health IT certification program and has no impact on providers' existing reporting practices for CMS quality programs. In the Information Blocking and ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency interim final rule with comment period (85 FR 70064), ONC finalized that health IT developers will have until December 31, 2022, to make updated certified technology available in accordance with revised criteria (85 FR 70066 through 70068).

In the FY 2022 IPPS/LTCH proposed rule (86 FR 25652), we proposed to require eligible hospitals and CAHs to use only certified technology updated consistent with the 2015 Edition Cures Update, as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25667), to submit data for eCQMs beginning with the reporting period in CY 2023. This is in alignment with the policy for the Hospital IQR Program discussed in section IX.C. of the preamble of this final rule. We refer readers to the ONC 21st Century Cures Act final rule for additional information about the updates included in the 2015 Edition Cures Update (85 FR 25666 through 25668). We also refer readers to the CY 2021 PFS final rule for the Medicare Promoting Interoperability Program (85 FR 84815 through 84825) and the Hospital IQR Program (85 FR 84825 through 84828), and section IX.C. of the preamble of this final rule for additional information related to this policy.

We invited public comments on our proposal to require eligible hospitals and CAHs to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for eCQMs, beginning with the reporting period in CY 2023, in alignment with the Hospital IQR Program proposal.

Comment: Several commenters supported the proposal to require use of 2015 Edition Cures Update beginning with the CY 2023 reporting period, citing that the requirement will help enhance data standardization, interoperability, and quality measurement. Commenters recommended CMS monitor vendor and hospital progress to ensure the transition to the 2015 Edition Cures Update remains feasible and exercise flexibility if there are vendor issues beyond the hospitals' control.

Response: We thank commenters for their support and agree with the statement that the 2015 Edition Cures Update aligns with the goals of the Medicare Promoting Interoperability Program on such issues. We will work with ONC to monitor the availability of EHR technology certified to the 2015 Edition Cures Update.

Comment: Several commenters did not support required use of the 2015 Edition Cures Update beginning with the CY 2023 reporting period citing insufficient time for hospitals to prepare and test for the requirement, and concern about health IT developers' timeline to develop and deploy technology.

Response: We appreciate commenters' concerns related to sufficient time for hospitals to prepare and test the 2015 Edition Cures Update after it is made available by health IT developer, however we respectfully disagree. The updates to the certification criteria that ONC finalized in the ONC 21st Century Cures Act final rule do not constitute a full new Edition of technology, as the scope of updates did not warrant implementation of an entirely new Edition of certification criteria (see 85 FR 84818 through 84825 for a more detailed discussion). The updates finalized in the ONC 21st Century Cures Act final rule are limited in scope to build on existing functionality and standards in technology certified to the 2015 Edition, which participants in the Medicare Promoting Interoperability Program have been using as part of clinical and administrative workflows since the CY 2019 reporting period (83 FR 41635 through 41636). We reiterate that the updates to the certification criteria do not impact providers' current reporting practices for eCQMs under the Medicare Promoting Interoperability Program, and, we intend to work with all our partners to monitor the timely availability of EHR technology certified to the 2015 Edition Cures Update.

After consideration of the public comments we received, we are finalizing our proposal to require eligible hospitals and CAHs to use only certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY 2023 reporting period to submit eCQM data for the Medicare Promoting Interoperability Program, in alignment with the Hospital IQR Program's policy.

X. Other Policy Provisions

A. Medicaid Enrollment of Medicare Providers and Suppliers for Purposes of Processing Claims for Cost-Sharing for Services Furnished to Dually Eligible Beneficiaries

1. Background

Dually eligible beneficiaries are those enrolled in both Medicare (either Part A, Part B, or both) and Medicaid. About 8 million dually eligible individuals are enrolled in the Qualified Medicare Beneficiary (QMB) program,[1374] which is a Medicaid benefit that assists low-income Medicare beneficiaries with Medicare Part A and Part B premiums and cost sharing. QMB ''Medicare cost-sharing'' amounts, as defined in section 1905(p)(3) of the Act,[1375] include Medicare Part A and B premiums, coinsurance, and deductibles. Section 1902(a)(10)(E) of the Act directs States to pay providers for Medicare coinsurance and deductibles. Under section 1905(p)(3) of the Act, ''Medicare cost-sharing'' includes costs incurred with respect to a QMB, regardless of whether the costs incurred were for items and services covered under the Medicaid State plan. Additionally, some State Medicaid agencies also elect to pay the Medicare cost-sharing for other (non-QMB) dually eligible beneficiaries.

However, section 1902(n)(2) of the Act permits the State to limit payment for Medicare cost-sharing to the amount necessary to provide a total payment to the provider (including Medicare, Medicaid State plan payments, and third-party payments) equal to the amount a State would have paid for the service under the Medicaid State plan. This is often referred to as the ''lesser-of'' policy.

If a State has adjudicated its Medicare cost-sharing to a provider pursuant to the lesser-of policy for an individual enrolled in the QMB program, section 1902(n)(3) of the Act prohibits the provider from collecting the remaining amount from the beneficiary.[1376] However, certain providers may recover a portion of these unpaid cost-sharing amounts as Medicare ''bad debt'' if they meet all the requirements in 42 CFR 413.89 and as described further in the Provider Reimbursement Manual Part 1 Chapter 3. Pursuant to § 413.89(h), bad debt payments are generally 65 percent of the uncollected amount for these services.

Per 42 CFR 413.89, providers must exclude any cost-sharing amount legally owed by the State from Medicare bad debt amounts claimed. CMS requires a provider that furnishes services to a dually eligible beneficiary to determine whether the State's Medicaid program (or applicable third party) is responsible for paying all or a portion of the beneficiary's Medicare deductible and/or coinsurance (and if so, how much) before the provider can claim these amounts as Medicare bad debt. Before claiming any unpaid cost-sharing amounts as a Medicare bad debt for a

[1374] Under 1905(p)(1) of the Act, a QMB is an individual who is entitled to hospital insurance benefits under Part A of Medicare, with income not exceeding 100 percent of the Federal poverty level, and resources not exceeding three times the SSI limit, adjusted annually by the Consumer Price Index. For more information about QMB eligibility and benefits, see chapter 1, section 1.6.2.1 and Appendices 1.A and 1.B of the Manual for the State Payment of Medicare Premiums.

[1375] A State's requirement to determine its cost-sharing liability for QMBs is also set forth at section 3490.14(A) of the State Medicaid Manual (SMM) (CMS Pub. 45).

[1376] Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions (see sections 1902(n)(3), 1905(p), 1866(a)(1)(A), and 1848(g)(3) of the Act).

dually eligible beneficiary, the provider must bill the State or State designee, such as a Medicaid managed care organization (MCO) (the ''must bill'' policy), and obtain from the State or State designee documentation of completed claim processing and claim adjudication information in the form of a Medicaid remittance advice (RA) [1377] that sets forth the State's cost-sharing liability for the items and services the beneficiary received (the ''RA'' policy).

2. Claims for Medicare Cost-Sharing for Dually Eligible Beneficiaries and Misaligned Medicare and Medicaid Provider Enrollment

Section 1903(a)(3)(A)(i) of the Act requires each State Medicaid Management Information System (MMIS) to process Medicare claims for dually eligible beneficiaries for Medicare cost-sharing. Furthermore, to comply with sections 1902(a)(10)(E) and 1902(n)(1) and (2) of the Act, the State MMIS must be able to process all such claims for Medicare cost-sharing liability even if the Medicaid State plan does not recognize a service or provider category.[1378] Nevertheless, some states in the past have inhibited enrollment of certain types of providers or suppliers that are not explicitly included in their State plan. If a Medicare-enrolled provider or supplier has been unable to enroll with the State Medicaid program, then the State MMIS may not adjudicate the cost-sharing claim and also may not return a Medicaid RA to the provider for the purposes of computing Medicare bad debt absent further actions by the State or by the provider.

To clarify states' obligations regarding claims for Medicare cost-sharing, we proposed to add a new paragraph (d) to 42 CFR 455.410 to clearly specify in regulation *how* States must meet this obligation. Specifically, we proposed that, for purposes of determining Medicare cost-sharing obligations, the State Medicaid programs must accept enrollment of all Medicare-enrolled providers and suppliers (even if a provider or supplier is of a type not recognized as eligible to enroll in the State Medicaid program) if the provider or supplier otherwise meets all Federal Medicaid enrollment requirements. These Federal requirements include, but are not limited to, all applicable provisions of 42 CFR part 455, subparts B and E. States must process claims from such providers requesting that the State determine its cost-sharing liability. States are already directed to issue RAs under section 11325.A of the State Medicaid Manual (stating that the Medicaid MMIS must produce remittance advice to providers) as part of their responsibility, already required pursuant to 42 CFR 433.112(b)(3), to process claims for dually eligible beneficiaries. We noted that neither this existing guidance nor the proposed provisions require States to recognize or enroll additional provider types for purposes other than submission of cost-sharing claims, adjudication of cost-sharing claims, and issuance of a Medicaid RA. Accordingly, we noted that States may wish to consider a separate enrollment process or provider enrollment category specifically for Medicare providers and suppliers for purposes of determining cost-sharing, consistent with existing law, acknowledging that individual States are in the best position to assess the feasibility of this or other possible approaches. We stated that we would leave it to States to determine how best to implement these requirements consistent with their system needs and capabilities, provisions of their Medicaid State plan and State law, and Federal Medicaid provider enrollment regulations and sub-regulatory guidance.[1379] However, we encouraged States to consult with CMS to help ensure their compliance with 42 CFR 455.410(d) and other Federal provider enrollment requirements related to this provision.

We proposed that State Medicaid programs and their applicable systems be in compliance with proposed § 455.410(d) in time to process cost-sharing claims for dually eligible beneficiaries with dates of service beginning January 1, 2023, recognizing that, despite current MMIS requirements, some States may need to make systems changes to comply. We noted that updates to the State MMIS are likely eligible for 90/10 Federal medical assistance percentage (FMAP) as set forth in 1903(a)(3)(A) of the Act. We stated that, if necessary, we will propose specific enforcement penalties for non-compliance in future rulemaking. We discuss Medicaid burden associated with these system changes in section I.H.9 of Appendix A of this final rule.

We noted that we believe that the requirements of proposed § 455.410(d) may reduce the number of future bad debt appeals by ensuring certain Medicare-enrolled providers and suppliers can enroll with State Medicaid programs, receive Medicaid Remittance Advice (RAs), and claim Medicare bad debt. In reducing these appeals, we stated that the provision would reduce the cost for providers to pursue such appeals and subsequent litigation, as well as the costs for CMS to defend them. Therefore, we estimate provider and Federal savings from avoiding future Medicare bad debt appeals. We discuss this reduction in provider and Federal burden in detail in section I.H.9 of Appendix A of this final rule.

Failure of State MMIS to provide a Medicaid RA for cost-sharing claims for dually eligible beneficiaries may also contribute to reduced access to care. Some providers may choose not to treat, or continue treating, dually eligible beneficiaries due to the provider burden associated with getting paid for cost-sharing claims; a decrease in providers willing to serve the dually eligible population could result in fewer health care options for beneficiaries. We noted that we believe this provision may have a positive impact on beneficiary access to care through reduced provider burden.

In response to this proposal, we received comments from close to 50 stakeholders, including States; hospital systems; physician, hospital, and LTCH associations; and beneficiary advocacy organizations. Most commenters supported this proposal. Several suggested additional modifications to Medicaid enrollment or State processing of claims for Medicare cost-sharing. Others sought technical clarifications. A few commenters expressed concerns about legality and burden. After review and consideration of these comments, we are finalizing this proposal as proposed. We summarize the major comments in this section of this rule:

Comment: Numerous commenters supported our proposal, describing difficulties providers experience trying to collect Medicaid RA and claim Medicare bad debt when the provider has difficulty enrolling with the state Medicaid agency. Commenters specifically noted this new policy would remove obstacles to providers

[1377] The FY 2021 Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System final rule (85 FR 58432), published on October 1, 2020, created the Medicaid RA alternative documentation policy with a retroactive effective date. This policy allows providers a way to submit alternative documentation to the Medicaid RA that sets forth the State's liability for the cost-sharing when a State does not process a Medicare crossover claim and issue a Medicaid RA to the provider. We anticipate the alternative documentation policy will only need to be in effect until States comply with the existing statute and process crossover cost-sharing claims for all Medicare providers. We would consider in future rulemaking removing the alternative once States comply with our proposal in this notice of proposed rulemaking.

[1378] *https://www.medicaid.gov/Federal-policy-guidance/downloads/cib-06-07-2013.pdf.*

[1379] Medicaid Provider Enrollment Compendium (MPEC).

and suppliers serving dually eligible beneficiaries, facilitate providers' ability to submit claims for Medicare bad debt, and better align state Medicaid enrollment and billing rules with the requirements of the Medicare ''must bill'' policy.

Response: We appreciate the support.

Comment: Some commenters sought clarification on whether this proposal applies to out-of-state providers.

Response: Under this policy, state Medicaid programs must accept enrollment of all Medicare-enrolled providers and suppliers, including out-of-state providers and suppliers, (even if a provider or supplier is of a type not recognized as eligible to enroll in the State Medicaid program) if the provider or supplier otherwise meets all Federal Medicaid enrollment requirements. These Federal requirements include, but are not limited to, all applicable provisions of 42 CFR part 455, subparts B and E. This policy does not require States to enroll out-of-state providers for purposes other than submission of cost-sharing claims, adjudication of cost-sharing claims, and issuance of a Medicaid RA.

Comment: Some commenters sought clarification on whether, under this proposal, States would be obligated to enroll ALL eligible Medicare providers and suppliers, or only those that apply to enroll in Medicaid. These commenters expressed concern that CMS will penalize States for those Medicare-enrolled providers and suppliers who choose not to enroll with the state Medicaid agency. A commenter expressed concern that Medicare-enrolled providers and suppliers will be required to enroll in-network with Medicaid MCOs.

Response: We understand that a Medicare-enrolled provider or supplier may choose not to enroll with a state Medicaid agency or as a Medicaid MCO network provider, and the State or Medicaid MCO cannot compel the provider or supplier to do so. Under this policy, CMS will not penalize States for non-enrollment of providers or suppliers who do not apply to enroll. Under this policy, state Medicaid programs must accept enrollment of all Medicare-enrolled providers and suppliers, including out-of-state providers and suppliers, (even if a provider or supplier is of a type not recognized as eligible to enroll in the State Medicaid program) if the provider or supplier otherwise meets all Federal Medicaid enrollment requirements. These Federal requirements include, but are not limited to, all applicable provisions of 42 CFR part 455, subparts B and E. This applies only to providers who chose to enroll in Medicaid for purposes of submission and adjudication of cost-sharing claims. We note that this policy does not require States to recognize or enroll additional provider types for purposes other than submission of cost-sharing claims, adjudication of cost-sharing claims, and issuance of a Medicaid RA.

Comment: Some commenters sought clarification on whether, under this proposal, States would be required to process cost-sharing claims for providers not enrolled in Medicaid and whether States would be required to enroll Medicare-providers and suppliers using Medicare claims and provider data for purposes of processing the cost-sharing claims. We also received several questions and comments about operational considerations related to State processing of claims for providers not enrolled in Medicaid.

Response: This provision does not require States to process claims for providers who do not enroll with the state Medicaid agency.

Comment: We received a few suggestions to expand upon this proposal to eliminate or streamline the Medicaid provider enrollment process. A commenter requested that CMS modify the proposal to allow States to make cost-sharing payments to Medicare-enrolled providers without screening or enrolling them in Medicaid. Similarly, another commenter requested CMS modify the proposal to allow the State to enroll a provider in Medicaid for the purposes of processing claims for cost-sharing without independently obtaining enrollment information, as long as the provider is enrolled in Medicare.

Response: Under current law, States can rely on the results of screening performed by Medicare if certain criteria are met. However, the State is still required to separately collect the disclosures and enroll the provider in their program in order to make payment to a provider. We appreciate these comments and are happy to work with the State on enrollment issues related to § 455.410(d), including opportunities to streamline enrollment.

Comment: A commenter opposed the proposed policy, writing that instead of requiring States to allow eligible Medicare providers to enroll in Medicaid, CMS should allow Medicare-only providers and suppliers to document their ineligibility as a Medicaid provider and submit it to CMS in order to facilitate payment for bad debt without a specific Medicaid RA indicating that the claim was not paid. This would require the provider to document the ineligibility for State payment once instead of maintaining Medicaid enrollment.

Response: Per sections 1902(a)(10)(E) and 1905(p)(3) of the Act, state Medicaid programs are liable for Medicare cost-sharing, including deductibles and co-insurance, for QMBs (and, if elected, certain other dually eligible individuals). And per 42 CFR 413.89, providers must exclude any cost-sharing amount legally owed by the State from Medicare bad debt amounts claimed. CMS understands that there are providers who never receive State payment of cost-sharing for the services they furnish; however, cost-sharing policy differs by state, service, and provider type, and changes over time. Therefore, per 42 CFR 413.89, to ensure the Medicare bad debt payments exclude the amounts Medicaid must pay, it is necessary for providers nationally to evidence state liability when claiming Medicare bad debt. We also encourage providers to consider whether they could submit alternative documentation pursuant to the policy finalized at 85 FR 58432.

Comment: Several commenters who supported the proposal suggested modifications to require States to make the effective dates of Medicaid provider enrollments under this regulation retroactive, to the greatest extent possible, and exempt from state Medicaid timely billing rules all claims submitted for dates of service back to those effective dates.

Response: We appreciate the commenters' support. This comment goes beyond the scope of the proposal. However, depending on applicable State law and policy, States may have the flexibility to implement additional changes per these suggestions as they modify their systems to comply with the new rule. We will continue to monitor and assess whether additional regulatory changes are needed as the policy is implemented.

Comment: Commenters noted that they appreciated CMS' encouragement for States to consider simplified enrollment forms for providers only seeking State payment of Medicare cost-sharing. They noted that filling out a multiple-page Medicaid enrollment form for what may well be a single interaction with a state Medicaid agency in a state on the other side of the country just to get a Medicaid RA with zero payment is an onerous burden and may lead both to less willingness to treat dually eligible individuals or improper and illegal attempts to get payment from the QMB individual.

Response: We appreciate the commenters' support and thank commenters for highlighting provider

burden and beneficiary access and protection issues. This comment goes beyond the scope of the proposal. We continue to encourage States to adopt a separate enrollment process or provider enrollment category specifically for Medicare providers and suppliers for purposes of determining cost-sharing, consistent with existing law. We are happy to work with States on these enrollment issues related to § 455.410(d).

Comment: A commenter indicated that current or planned claims system upgrades may impede a State's ability to enact required changes by the January 2023 deadline.

Response: While we understand that States have limited resources to implement systems changes, we continue to believe that an implementation date of January 1, 2023 allows States ample time to come into compliance. Updates to the State MMIS are likely eligible for 90/10 Federal medical assistance percentage (FMAP) as set forth in 1903(a)(3)(A) of the Act. As noted in the proposed rule, if necessary, we will propose specific enforcement penalties for non-compliance in future rulemaking.

Comment: A commenter urged CMS to strengthen its work to improve processing of claims for cost-sharing and bad debt, and to ensure States are not imposing undue burden on providers in the enrollment process. This commenter suggested CMS finalize this regulation as part of more comprehensive monitoring and enforcement of the existing statutory requirements.

Response: CMS is committed to improving access to care for dually eligible individuals, which includes reducing burden and promoting payment equity for the providers who serve them. As noted in the proposed rule, if necessary, we will propose specific enforcement penalties for non-compliance in future rulemaking.

Comment: Commenters encouraged the continuation of the Medicaid RA alternative documentation policy developed in the FY 2021 IPPS rulemaking for the foreseeable future, suggesting that it provides necessary pragmatic flexibility to providers that would otherwise be disadvantaged by a State's failure to issue a Medicaid RA, whether that failure is due to inappropriate enrollment restrictions or other processes that result in the failure to properly process certain types of crossover cost-sharing claims.

Response: The policy finalized at 85 FR 58432 is still in effect. In sum, that policy created the Medicaid RA alternative documentation policy with a retroactive effective date, to allow providers a way to submit alternative documentation to the Medicaid RA that sets forth the State's liability for the cost-sharing when a State does not process a Medicare crossover claim and issue a Medicaid RA to the provider.

Comment: A commenter, citing section 1902(kk) of the Act, wrote that CMS exceeded its authority by requiring States to enroll providers who meet Medicare requirements and Federal Medicaid requirements, but who might not meet state Medicaid requirements. This commenter was concerned that the proposed changes would limit the ability of the State to implement additional screening requirements outlined in state-specific law and would force the State to enroll Medicare providers who would otherwise be excluded for violations of various state criminal laws.

Response: As stated in section X of this final rule, this new regulation only requires that States enroll eligible Medicare-enrolled providers and suppliers for the purposes of adjudicating and paying Medicare cost-sharing; States do not need to enroll eligible Medicare-enrolled providers and suppliers for all purposes on par with Medicaid providers and suppliers that get paid by the State for furnishing Medicaid State plan services. As such, we believe it is appropriate to apply only the Federal Medicare and Medicaid enrollment requirements. We note that, per 42 CFR 424.530(a)(3) and 424.535(a)(3), CMS denies and revokes a provider or supplier's Medicare-enrollment based upon certain State or Federal felony convictions.

Comment: A commenter noted that the authorities relevant to this proposal included in the proposed rule were incomplete and should be corrected.

Response: We corrected the authorities to section I.A.1 to include Section 1902(kk)(3) of the Act and Section 2107(e)(1) of the Act.

Comment: A commenter questioned if CMS maintains a list of Medicare-enrolled provider types with a crosswalk to Medicaid-enrolled provider types.

Response: States may reference the Medicare Claims Processing Manual [1380] to review the Medicare-enrolled providers and supplier types.

Comment: A few commenters requested additional clarification regarding how this proposal impacts specific claims processing and payment methodologies. A commenter questioned how this proposal would impact instances where the allowed amount for the Medicaid service is less than what Medicare has already paid or instances where the State either does not offer additional payment or does not cover the service. Another commenter questioned if additional fee schedules are required for provider types that are not currently covered by the State plan.

Response: States should adjudicate cost-sharing claims for dually eligible beneficiaries per their approved Medicaid State plan; Medicaid State plans detail payment methodologies for services not covered by the Medicaid program. We are happy to work with States to discuss approvable methodologies or potential revisions to the Medicaid State plan.

Comment: Several commenters urged CMS and Congress to continue improving policies regarding dually eligible beneficiaries and provider payment by eliminating the lesser-of policy. Commenters explained that the lesser-of policy creates a financial penalty every time a provider serves a dually eligible beneficiary as the provider does not receive full, equitable payment for services. Commenters noted that this disincentivizes providers from serving dually eligible beneficiaries, further impacting the access to care inequities of dually eligible beneficiaries.

Response: Eliminating the lesser-of policy is beyond the scope of the proposal, but CMS thanks commenters for these recommendations and affirms our commitment to improve access and equity for dually eligible beneficiaries.

As previously noted, after consideration of the public comments we received, we are finalizing our proposal to add a new paragraph (d) to 42 CFR 455.410 to clearly specify in regulation that the State Medicaid agency must allow enrollment of all Medicare enrolled providers and suppliers for purposes of processing claims to determine Medicare cost-sharing (as defined in section 1905(p)(3) of the Act) if the providers or suppliers meet all Federal Medicaid enrollment requirements, including, but not limited to, all applicable provisions of 42 CFR part 455, subparts B and E. This paragraph (d) applies even if the Medicare-enrolled provider or supplier is of a type not recognized by the State Medicaid Agency. State Medicaid programs and their applicable systems must be in compliance with § 455.410(d) in time to process cost-sharing claims for dually eligible beneficiaries with dates of service beginning January 1, 2023.

[1380] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf.*

In the proposed rule we noted that, in addition to certain Medicare-recognized provider and supplier types having difficulty enrolling in some Medicaid programs for purposes of submitting cost-sharing claims, we understand that some providers report that some States may not process certain cost-sharing claims for services that are payable by the State under the terms of the Medicaid State plan. We noted that we had received feedback from providers that some States determine their cost-sharing liability for a Medicare service by applying the Medicaid payment and coverage rules for the service as if the service (rather than the cost-sharing) were being paid by Medicaid. This means that the State MMIS will reject, deny, or return zero liability for a claim for Medicare cost-sharing unless the provider completes Medicaid documentation and meets Medicaid coverage and payment standards. For example, a provider submits a claim for oxygen therapy for use in home with a lifetime length of need and the claim meets Medicare payment and coverage standards.[1381] When the provider submits this claim for Medicaid payment of cost-sharing (or when Medicare ''crosses over'' the claim to the State), the State denies the claim because the claim does not meet the State's conditions of Medicaid payment for oxygen therapy (that is, the provider must complete and sign a State's Medicaid certificate of medical necessity or certificate of need, which requires different Medicaid coding and modifiers, and has a maximum length of need of 12 months). A State operational policy like this creates unnecessary work for providers, suppliers, and beneficiaries. It could also prevent the State from meeting its actual cost-sharing liability. Building on the provider enrollment requirement in proposed § 455.410(d), we considered proposing a policy that States must process claims for Medicare cost-sharing without requiring that the claim meet the Medicaid State plan coverage and payment rules for that service. Instead, we requested additional feedback from stakeholders on the scope of this practice, including State and service specific examples, and noted we will consider whether to include such a policy or otherwise address the issue in future rulemaking.

Several commenters wrote to offer their support for a proposal to require States to process claims for Medicare cost-sharing without requiring that the claim meet the Medicaid State plan coverage and payment rules for that service. None commented in opposition. We will continue to consider this issue for future rulemaking.

C. Medicare Shared Savings Program—Policy Changes (§ 425.600)

1. Background

The Medicare Shared Savings Program (Shared Savings Program) was established under section 1899 of the Act to facilitate coordination and cooperation among providers and suppliers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an accountable care organization (ACO). The regulations implementing the Shared Savings Program are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802)). A complete list of all of the statutes and regulations pertaining to the Shared Savings Program is located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-statutes-and-regulations*.

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** titled ''Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017'' (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share in savings and are accountable for repaying shared losses); new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the December 2018 final rule, we established the BASIC track in a new provision at § 425.605. The BASIC track includes an option for eligible ACOs to begin participation under a one-sided model and incrementally phase-in risk (using a loss recoupment limit calculated based on ACO participant revenue and capped at a percentage of the ACO's updated benchmark) and potential reward over the course of a single agreement period, an approach referred to as the glide path (83 FR 67841). The glide path includes five levels: A one-sided model available only for the first 2 consecutive performance years (PYs) of an ACO's initial 5-year agreement period, each year of which is identified as a separate level (Levels A and B); and three levels of progressively higher risk and potential reward in PYs 3 through 5 of the agreement period (Levels C, D, and E). Eligible ACOs that have previously participated in Track 1 of the Shared Savings Program may enter the glide path at Level B. ACOs are automatically advanced along the progression of risk/reward levels at the start of each performance year, over the course of a 5-year agreement period, unless the ACO elects to advance more quickly, until ACOs reach the BASIC track's maximum level of risk/reward (Level E) (83 FR 67844). Level E qualifies as an Advanced Alternative Payment Model and clinicians in ACOs participating in Level E of the BASIC track may qualify for APM incentive payments under the Quality Payment Program if they meet the criteria to become Qualifying APM Participants (QPs). For ACOs that entered the BASIC track's glide path for an agreement period beginning on July 1, 2019, the progression through the levels of risk and potential reward spans 6 performance years, including the ACO's first performance year from July 1, 2019, through December 31, 2019; these ACOs were not automatically advanced to the next risk/reward level at the start of PY 2020 (for more information, see §§ 425.200(b)(4)(ii) and (c)(3) and 425.600(a)(4)(i)(B)(2)(i)).

As of January 1, 2021, there are 477 Shared Savings Program ACOs serving approximately 10.7 million Medicare FFS beneficiaries across the country: 41 percent of ACOs (195 of 477) are currently participating under two-sided shared savings and shared losses models; and 194 ACOs are participating under the BASIC track's glide path, including 163 ACOs in one-sided Levels A and B and 31 ACOs in two-sided Levels C and D. For PY 2021, 6 ACOs elected to advance more quickly along the glide path to Level E for a total of 69 ACOs currently participating under Level E of the BASIC track.

The COVID–19 pandemic and the resulting ongoing public health emergency (PHE), as defined in 42 CFR

[1381] We note that any remaining unpaid deductible and coinsurance amounts associated with oxygen and oxygen equipment paid under a Medicare fee schedule cannot be an allowable Medicare bad debt.

400.200, have continued to create a lack of predictability for many ACOs regarding the impact of utilization changes on beneficiary assignment and performance year expenditures. The PHE has disrupted population health activities as clinicians, care coordinators and financial and other resources are diverted to address immediate needs, including acute care and vaccine delivery. The lack of predictability and disrupted population health activities created concern for some ACOs regarding the impact on their Shared Savings Program performance and the potential for shared losses. In the interim final rule with comment period (IFC) that appeared in the May 8, 2020 **Federal Register** (85 FR 27575 and 27576) (hereinafter referred to as the ''May 2020 COVID–19 IFC''), we modified the Shared Savings Program policy of automatic advancement along the glide path to allow BASIC track ACOs participating in the glide path the option to forgo the first automatic advancement along the glide path's increasing levels of risk and potential reward. We subsequently finalized the modified policy without change in the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84767 through 84769). Under the terms of the current regulations, BASIC track ACOs that elected this option for performance year 2021 will be automatically advanced for performance year 2022 to the level at which they would have otherwise participated under automatic advancement if they had not elected the option. Seventy-four percent of eligible BASIC track ACOs (148 of 201) elected the 1-year ''freeze'' for PY 2021. Another 18 BASIC track ACOs elected to take on risk, by either automatically transitioning to Level C or by advancing more quickly along the glide path.

2. Basic Track Risk ''Freeze'' Option for PY 2022

Due to the continued PHE for COVID–19, ACOs and other stakeholders requested that the exception that allowed ACOs in the BASIC track to opt for a risk ''freeze'' for PY 2021 be continued for PY 2022. While the PHE for COVID–19 remains ongoing, new considerations and challenges that impact ACO operations and expenditures continue to emerge: (1) The effects of cancelling or delaying services during the PHE, including the expectation that beneficiaries who may have gone without routine and acute care during the PHE will need increased care; (2) the emergence of new variants and mutations of the existing variants of the coronavirus that causes COVID–19; and (3) the resources involved in vaccinating the Medicare population. Given the inability of ACOs to anticipate the extent to which these issues may impact expenditures during PY 2022 and effectively prepare for these issues, we believe providing additional flexibilities to address the uncertainty produced by the ongoing PHE for COVID–19 is essential to encourage ACOs to continue participating in the Shared Savings Program during the ongoing PHE for COVID–19.

As noted previously, in the May 2020 COVID–19 IFC, we adopted a new provision at § 425.600(a)(4)(i)(B)(2)(iii) to provide the opportunity for ACOs participating in the BASIC track's glide path to maintain their level of participation for PY 2021 and not automatically progress to a higher level along the glide path. For PY 2022, the ACOs that voluntarily elected to ''freeze'' their participation level in accordance with § 425.600(a)(4)(i)(B)(2)(iii) are currently required to progress to the level of participation they would have been automatically advanced to, absent the election to maintain their participation level for PY 2021. For example, if an ACO in Level B of the BASIC track in PY 2020 elected to maintain its participation in Level B for PY 2021, the ACO will be automatically transitioned to Level D for PY 2022. Level D of the BASIC track is a two-sided model with a 50-percent sharing rate and 30-percent loss sharing rate, not to exceed 4 percent of ACO participant revenue capped at 2 percent of the ACO's updated benchmark.

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25677), stakeholders have expressed concern that as a result of the unpredictable circumstances of the PHE and the sustained impacts of the COVID–19 pandemic during PY 2021, some ACOs may terminate their participation in the program if they are required to automatically transition to downside risk or a higher level of downside risk for PY 2022. Specifically, stakeholders requested that we allow a second ''freeze'' to permit ACOs participating in the BASIC track's glide path to opt out of automatic advancement from their current level of participation for PY 2022.

As detailed in the May 2020 COVID–19 IFC (85 FR 27576), per § 425.204(f)(3)(iii), an ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate, or is automatically transitioned to a two-sided model of the BASIC track, including Level C, Level D or Level E. In the FY 2022 IPPS/LTCH PPS proposed rule, we expressed our belief that it would be appropriate to provide the flexibility to ACOs, particularly those that would otherwise automatically transition to Level C or D of the BASIC track for PY 2022, to delay transitioning to two-sided risk, thus delaying the requirement to establish a repayment mechanism prior to the start of PY 2022. This flexibility would allow these ACOs the option to put financial resources that might otherwise be used to establish a repayment mechanism towards continuing to care for their beneficiaries during the ongoing pandemic. Currently, the Shared Savings Program has 163 ACOs participating under Level A or Level B of the BASIC track that are scheduled to automatically advance to Level C or Level D on January 1, 2022.

We also expressed concern that the PHE for COVID–19 has made expenditures and utilization more difficult to predict and that ACOs may be more risk-averse as patient care patterns have been altered by the pandemic. ACOs cannot know the full impact that the PHE for COVID–19 and the related changes in health care utilization will have on their total expenditures or their assigned beneficiary population. In addition, we noted that the duration of the PHE for COVID–19 remained uncertain, and it is unclear whether the PHE will extend into 2022, such that shared losses owed by ACOs participating under two-sided payment models would be mitigated under the Shared Savings Program's extreme and uncontrollable circumstances policy. Therefore, we proposed that ACOs participating in the BASIC track's glide path may elect to maintain their current level of risk under the BASIC track for PY 2022. Specifically, we proposed that before the automatic advancement for PY 2022, an applicable ACO may elect to remain in the same level of the BASIC track's glide path in which it participated during PY 2021. For PY 2023, an ACO that elects this advancement deferral option would be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2023 if it had advanced automatically to the required level for PY 2022 (unless the ACO elects to advance more quickly before the start of PY 2023). For example, if an ACO that participated in the BASIC track Level A for PY 2020, then automatically advanced to Level B in PY 2021, elects to maintain its

current level of participation for PY 2022, it would participate under Level B for PY 2022 and then would automatically advance to Level D for PY 2023. The ACO could also elect to advance more quickly by opting to move to Level E instead of Level D for PY 2023, in which case the ACO would participate under Level E for the remainder of its agreement period. In contrast, if an ACO that participated in the BASIC track Level B for PY 2020 elected to maintain its participation at Level B for PY 2021, but does not elect to maintain its participation under Level B for PY 2022, the ACO would automatically advance to Level D for PY 2022, unless it chooses to advance more quickly.

Under this proposal, an ACO that elects to freeze its participation level for both PY 2021 and PY 2022 would be automatically advanced for PY 2023 to the level of the BASIC track's glide path in which it would have participated during PY 2023, absent both of its elections to freeze. For example, if an ACO participating in the BASIC track, Level B, in PY 2020 elected to maintain its current level of participation for PY 2021, and then chose again to maintain its current level of participation for PY 2022, it would continue to participate under Level B in both PY 2021 and PY 2022, before automatically advancing to Level E for PY 2023. In this example, the ACO would participate under Level E for the remainder of its agreement period. We provided the following table to illustrate the potential scenarios for ACOs that elect to maintain their current level of risk for PY 2021 or PY 2022 or both. This chart is intended only to address ACOs that may want to elect to ''freeze'' for PY 2022 and does not address other participation options, such as the exception that allows certain ACOs to elect to remain in Level B for an additional performance year, and then automatically advance to Level E for the final 2 participation years of their agreement period as specified at § 425.600(a)(4)(i)(B)(2)(ii).

BASIC TRACK'S GLIDE PATH "FREEZE" SCENARIOS			
PY 2020	**PY 2021**	**PY 2022**	**PY 2023**
Level A	Maintained at Level A	Maintain at Level A	Progress to Level D
		Progress to Level C	
	Progressed to Level B	Maintain at Level B	
		Progress to Level C	
Level B	Maintained at Level B	Maintain at Level B	Progress to Level E
		Progress to Level D	
	Progressed to Level C	Maintain at Level C	
		Progress to Level D	
Level C	Maintained at Level C	Maintain at Level C	Progress/Maintain Level E
		Progress to Level E	
	Progressed to Level D	Maintain at Level D	
		Progress to Level E	
Level D	Maintained at Level D	Maintain at Level D	Progress/Maintain Level E
		Progress to Level E	
	Progressed to Level E	Maintain Level E	

We proposed that the ACO's voluntary election to maintain its participation level for PY 2022 must be made in the form and manner and by a deadline established by CMS, and an ACO executive who has the authority to legally bind the ACO must certify the election.

We proposed to redesignate § 425.600(a)(4)(i)(B)(*2*)(*iv*) as § 425.600(a)(4)(i)(B)(*2*)(*v*). Additionally, we proposed to add a new § 425.600(a)(4)(i)(B)(*2*)(*iv*) to allow ACOs currently participating in the BASIC track's glide path to elect to maintain their current participation level for PY 2022. We also noted that we intended to continue to monitor the PHE for COVID–19 and assess its impact on the Shared Savings Program, and explained that we would address any additional flexibilities that may be warranted as a result of the ongoing PHE through future notice and comment rulemaking.

Lastly, we noted that in the May 2020 COVID–19 IFC (85 FR 27625), we revised the regulations at § 425.600 to allow BASIC track ACOs to maintain their participation level for PY 2021 by redesignating paragraph (a)(4)(i)(B)(*2*)(*iii*) as paragraph (a)(4)(i)(B)(*2*)(*iv*) and adding a new paragraph (a)(4)(i)(B)(*2*)(*iii*). However, we inadvertently omitted the revision to the cross-reference in paragraph (a)(4)(i)(B)(*3*). In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to make further revisions to § 425.600(a)(4)(i)(B)(*2*), which would also affect the cross-reference in paragraph (a)(4)(i)(B)(*3*). Therefore, we proposed to revise § 425.600(a)(4)(i)(B)(*3*) to remove the reference to paragraph (a)(4)(i)(B)(*2*)(*iii*) and replace it with a reference to paragraph (a)(4)(i)(B)(*2*)(*v*).

Comment: Many commenters expressed support for CMS' proposal to permit eligible ACOs to voluntarily elect to maintain their level of risk/reward within the BASIC track's glide path for PY 2022, and particularly appreciated the additional stability and flexibility that this option would afford them.

Response: We appreciate commenters' support for allowing ACOs participating in the BASIC track's glide path the opportunity to elect to remain in the same level of the BASIC track's glide path in which they participated for PY 2021, for PY 2022.

Comment: A number of commenters urged CMS to reconsider our decision to move ACOs at the start of PY 2023 to the level of risk in which they would have participated for PY 2023, absent the freeze. Commenters expressed concern that skipping a level would be challenging under normal circumstances, but the COVID–19 PHE has involved continued, extenuating circumstances, the effects of which on cost and quality remain to be seen. Therefore, according to these commenters, finalizing this automatic advancement policy would not allow ACOs sufficient opportunity to focus on recovering financially and on patient care, and would jeopardize an ACO's ability to both remain and succeed in the program. These commenters recommended instead that ACOs that elect to freeze their participation level for PY 2022 at their current level for PY 2021 should enter PY 2023 at the level of the BASIC track glide path that they would have entered for PY 2022, absent the freeze.

Response: Of the BASIC track ACOs that are participating in PY 2021, 75 percent are in a second or subsequent agreement period. All of these ACOs have prior experience participating in the Shared Savings Program; some of these ACOs have participated in the program continuously since 2012. Although the PHE for COVID–19 has presented unprecedented challenges and diverted ACO attention and resources from improving quality and lowering costs of care for their assigned beneficiaries, which justifies the ''freeze'' policy for eligible ACOs participating on the BASIC track's glide path for PY 2021 and PY 2022, we believe that by gaining additional experience in the Shared Savings Program during performance years 2021 and 2022 within the context of the PHE for COVID–19, ACOs are more prepared to progress to higher levels of risk and potential reward within the BASIC track's glide path beginning in PY 2023, if not sooner, at the ACO's election. ACOs have managed dynamic circumstances during the pandemic, shifting focus from preventive and maintenance care to testing and treating beneficiaries for COVID–19, and the delivery of the COVID–19 vaccine, as well as transitioning health care providers from in-person healthcare visits to telehealth. In addition, we believe that it is beneficial for ACOs to participate in the highest levels of the BASIC Track prior to renewing in a new agreement period where they would be required to participate in the ENHANCED Track or Level E of the BASIC Track. For example, a Level A ACO that elected the option to maintain their risk level for both PY 2021 and PY 2022, would then advance to Level D for PY 2023, providing the opportunity to participate at a more moderate level of risk before having to advance to the highest level of risk under the basic track, Level E. As noted previously, we intend to continue to monitor the PHE for COVID–19 and assess its impact on the Shared Savings Program, and we will address any additional flexibilities that may be warranted through future notice and comment rulemaking.

Therefore, at this time, we decline commenters' suggestions that we further slow ACOs' progression along the BASIC track's glide path by allowing ACOs that elect to maintain their current position on the glide path for PY 2022 to resume their progression at the level they would have entered for PY 2022, absent the freeze.

Comment: Some commenters expressed concern that, given the timing of the application cycle and the display of the final rule, ACOs would have insufficient time and information available before having to decide whether to freeze their participation level or advance along the glide path and submit a repayment mechanism.

Response: The FY 2022 IPPS/LTCH PPS proposed rule was available for public inspection via of the Office of the Federal Register on April 27, 2021. Therefore, we believe ACOs have had sufficient time to review the proposed policy and determine their preferred participation option for PY 2022. As discussed in the proposed rule (86 FR 25679), we gave ACOs the opportunity during the change request cycle for PY 2022 to indicate whether they were interested in maintaining their current level of participation in the event the proposed policy were to be finalized for PY 2022. During the PY 2022 Change Request Cycle Phase 1 initial submission period, 79 out of 176 (45 percent) of eligible ACOs indicated interest in maintaining participation at their current level for PY 2022. This election will remain available through the Phase 1 second request for information (Phase 1 RFI–2) due by noon Eastern Daylight Time on September 10, 2021. We also began educating ACOs about this proposed policy after the April 27, 2021 public filing of the FY 2022 IPPS/LTCH PPS proposed rule. The potential for an election to ''freeze'' was communicated to currently participating ACOs via the ACO Spotlight Newsletter, our ACO-Management System and via conversations with our ACO coordinators.

As a result, we do not believe providing additional time for ACOs to determine their preferred participation option for PY 2022 is necessary, as ACOs have had time to consider their options, and whether they prefer to elect to maintain their participation level for PY 2022. Furthermore, ACOs that elect to remain at their current participation level, but that would otherwise have been required to enter two-sided risk in PY 2022 will not need additional time to secure a repayment mechanism. ACOs that do not elect to freeze their current participation level for PY 2022 and that will advance to a two-sided model for PY 2022 should have already anticipated the requirement to have a repayment mechanism ready for PY 2022 and started taking the necessary steps to establish one.

Comment: A commenter opposed the proposed policy to allow eligible ACOs to maintain their current risk level, citing that the COVID–19 pandemic has eased significantly in 2021 as a result of widely available and effective vaccines, and suggested that such an accommodation under the current circumstances was unnecessary.

Response: We appreciate the commenter's feedback. However, we decline to modify the proposal with respect to PY 2022, which we are finalizing as proposed. According to other commenters, the COVID–19 PHE continues to affect ACO operations, as ACO participants seek to balance their response to the PHE, while also managing normal operations, implementing care redesigns and improving the quality of care provided to beneficiaries. As a result, we continue to believe allowing eligible ACOs to maintain their current risk level for PY 2022 is a necessary flexibility that will afford ACOs additional stability as they continue to deal with the effects of the PHE.

Comment: A few of the comments received were out outside the scope of this rulemaking, including comments concerning quality reporting and the use of reinsurance as a repayment mechanism.

Response: Comments of this nature are beyond the scope of the policies discussed in the proposed rule and are not being addressed in this final rule.

After considering the comments received, we are finalizing the proposed policy without modification. Accordingly, we are finalizing the redesignation of § 425.600(a)(4)(i)(B)(2)(iv) as § 425.600(a)(4)(i)(B)(2)(v) and the addition of a new § 425.600(a)(4)(i)(B)(2)(iv) to allow ACOs currently participating in the

BASIC track's glide path to elect to maintain their current participation level for PY 2022. We did not receive comments on the proposal to revise § 425.600(a)(4)(i)(B)(3) to remove the reference to paragraph (a)(4)(i)(B)(2)(iii) and replace it with a reference to paragraph (a)(4)(i)(B)(2)(v); and therefore, we are also finalizing this revision as proposed without modification.

XI. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2021 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2022 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at: *http://www.medpac.gov*.

XII. Other Required Information

A. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.* We listed the data files available in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25679 through 25681).

Commenters interested in discussing any data files used in construction of this final rule should contact Michael Treitel at (410) 786–4552.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the FY 2022 IPPS/LTCH PPS proposed rule, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs Relating to the Hospital Readmissions Reduction Program

In section V.G. of the preamble of this final rule, we discuss requirements for the Hospital Readmissions Reduction Program. In this final rule, we are not removing or adopting any new measures into the Hospital Readmissions Reduction Program for FY 2022. All six of the current Hospital Readmissions Reduction Program's measures are claims-based measures. We believe that continuing to use these claims-based measures would not create or reduce any information collection burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes.

In section V.G.6. of the preamble of this final rule, we are finalizing our proposal to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) due to the significant impact of the COVID–19 PHE on this measure, for FY 2023, as well as technical measure specification updates to the five remaining condition/procedure-specific readmission measures. However, we believe that the updates to these claims-based measures would not create or reduce any information collection burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes.

We did not receive comments regarding the ICRs for the Hospital Readmissions Reduction Program.

3. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section V.H. of the preamble of the final rule, we discuss our finalized requirements for the Hospital VBP Program. Specifically with respect to quality measures, we are finalizing our proposals to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, Medicare Spending per Beneficiary (MSPB), and the five hospital-acquired infection (HAI) measures for the FY 2022 program year. We are also finalizing the removal of the CMS PSI 90 measure beginning with the FY 2023 program year and our proposal to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN) measure for the FY 2023 program year. Because the FY 2022 and FY 2023 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare FFS claims data that hospitals are already submitting to CMS for payment purposes, we stated in the proposed rule that we did not anticipate any change in burden associated with these policies.

We did not receive any comments regarding the ICRs for the Hospital VBP Program and are finalizing our proposals without modification.

4. ICRs for the Hospital Acquired Condition (HAC) Reduction Program

In this rule, we are not removing any measures, adopting any new measures into the HAC Reduction Program, or updating our validation procedures.[1382] The HAC Reduction Program has previously adopted six measures: The CMS PSI 90 measure and five CDC NHSN HAI measures. We do not believe that the claims-based CMS PSI 90 measure in the HAC Reduction Program creates or reduces any burden for hospitals because it is collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes. Accordingly, we do not believe that our policy, finalized in section V.I.3.d. of the preamble of this final rule, to suppress third and fourth quarter CY 2020 data from the CMS PSI 90 measure from FY 2023 and FY 2024 Total HAC Scores create or reduce any information collection burden for hospitals.

We note that the burden associated with collecting and submitting data for the remaining five measures, the HAI

[1382] Burden associated with the validation procedures in the HAC Reduction Program are accounted for under OMB Control Number 0938–1352.

measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA bacteremia, and CDI) via the NHSN system is captured under a separate OMB control number, 0920–0666 (expiration November 30, 2021), and therefore our finalized policy to suppress third and fourth quarter CY 2020 data from these measures from FY 2022 and FY 2023 Total HAC Scores did not impact our burden estimates.

We did not receive comments regarding the ICRs for the HAC Reduction Program.

5. ICR for Repeal of Market-Based MS–DRG Relative Weight Data Collection

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a requirement for a hospital to report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021 (85 FR 58873 through 58892); this data collection requirement was specified in 42 CFR 413.20(d)(3). Instructions for the reporting of this market-based data on the Medicare cost report were discussed in the revision of the currently approved OMB control number 0938–0050 published on November 10, 2020 (for more information we refer readers to (*https://www.federalregister.gov/documents/2020/11/10/2020-24948/agency-information-collection-activities-proposed-collection-comment-request* and *https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-2552-10*).

As discussed in section V.L. we are repealing this market-based data collection requirement and the market-based MS–DRG relative weight methodology that was adopted effective for FY 2024, and will continue using the existing cost-based methodology for calculating the MS–DRG relative weights for FY 2024 and subsequent fiscal years. In the FY 2021 IPPS/LTCH PPS final rule, we estimated an annual burden per hospital and estimated total annual burden for all hospitals to comply with the requirements previously set forth in 42 CFR 413.20(d)(3) (85 FR 59015). These burden estimates were never approved.

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. OMB has currently approved 1,572,443 hours of burden and approximately $61 million under OMB control number 0938–1022, accounting for information collection burden experienced by approximately 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2023 payment determination. In the proposed rule (86 FR 25682) and this final rule, we describe the burden changes regarding collection of information under OMB control number 0938–1022 (expiration date December 31, 2022) for IPPS hospitals.

For more detailed information on our finalized policies for the Hospital IQR Program, we refer readers to section IX.C. of this final rule. We are finalizing most of our proposals which will affect the information collection burden associated with the Hospital IQR Program. As discussed, we are finalizing the adoption of two measures that we expect to affect our collection of information burden estimates: (1) The Maternal Morbidity structural measure beginning with a shortened reporting period from October 1 through December 31, 2021 (affecting the FY 2023 payment determination), followed by annual reporting periods for subsequent years; and (2) the Hybrid Hospital-Wide All-Risk Standardized Mortality measure with Claims and Electronic Health Record Data (Hybrid HWM measure) beginning with a one-year voluntary reporting period (July 1, 2022 through June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023 through June 30, 2024 reporting period/FY 2026 payment determination. Details on these policies as well as the expected burden changes are discussed further in this section of this final rule.

We are also finalizing several policies which would not affect the information collection burden associated with the Hospital IQR Program. As discussed in section IX.C. of the preamble to this final rule, we are finalizing our proposals to: (1) Adopt the Maternal Morbidity structural measure beginning with a shortened reporting period from October 1 through December 31, 2021 (affecting the FY 2023 payment determination), followed by annual reporting periods (affecting the FY 2024 payment determination and subsequent years); (2) adopt the Hospital Harm—Severe Hyperglycemia electronic clinical quality measure (eCQM) beginning with the CY 2023 reporting period/FY 2025 payment determination; (3) adopt the Hospital Harm—Severe Hypoglycemia eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination; (4) adopt the COVID–19 Vaccination Coverage among HCP measure beginning with a shortened reporting period from October 1 to December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination; (5) remove the Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) eCQM measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) remove the Exclusive Breast Milk Feeding (PC–05) eCQM measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) remove the Discharged on Statin Medication (STK–06) eCQM measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (8) revise the Program's regulations at 42 CFR 412.140(a)(2) by replacing the term ''QualityNet Administrator'' with the term ''QualityNet security official'' and 42 CFR 412.140(e)(2)(iii) by replacing the term ''QualityNet system administrator'' with the term ''QualityNet security official''; (9) revise the Program's regulations at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i) to remove references to ''*QualityNet.org*'' and replacing it with ''QualityNet website''; (10) require the use of the 2015 Edition Cures Update for certification criteria beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years for both eCQMs and hybrid measures; and (11) extend the effects of educational reviews for fourth quarter data such that if an error is identified during the education review process for fourth quarter data, we would use the corrected quarterly score to compute the final confidence interval used for payment determination beginning with validations affecting the FY 2024 payment determination. As discussed in the preamble of this final rule, we do not expect these provisions to affect our information collection burden estimates. We note that we are not finalizing our proposals to remove: The Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03) eCQM; and the Death Rate Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) Claims-Based Measure.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 59008), we estimated that reporting measures for the Hospital IQR Program could be accomplished by staff with a median hourly wage of $19.40 per hour. We note that since then, more recent wage data have become available, and we are updating the wage rate used

in these calculations in this proposed rule. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $20.50 per hour for a medical records and health information technician professional.[1383] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($20.50 × 2 = $41.00) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of $41.00 per hour throughout the discussion in this section of this rule for the Hospital IQR Program.

b. Information Collection Burden Estimate for the Maternal Morbidity Structural Measure

In section IX.C.5.a. of the preamble of this final rule, we are finalizing the adoption of the Maternal Morbidity Structural measure beginning with the CY 2021 reporting period/FY 2023 payment determination as proposed. The shortened data submission period for the Maternal Morbidity structural measure would run from October 1 through December 31, 2021, followed by annual reporting periods for subsequent years. Reporting on the Maternal Morbidity structural measure will involve each hospital responding to a single question using a web-based tool available via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System) with one of the following response options: (A) ''Yes''; (B) ''No''; or (C) ''N/A (our hospital does not provide inpatient labor/delivery care).''

We are finalizing our proposal to require hospitals to submit the response on an annual basis during the submission period. In summary, because we are finalizing our proposal in section IX.C.5.a. of the preamble of this final rule to adopt the Maternal Morbidity structural measure, we estimate the information collection burden associated with this finalized structural measure to be no more than 5 minutes per hospital per year, as it involves responding to a single question one time per year for a given reporting period. Using the estimate of 5 minutes (or 0.083 hours) per hospital per year, and the updated wage estimate as described previously, we estimate that this policy will result in a total annual burden increase of 275 hours across all 3,300 IPPS hospitals (0.083 hours × 3,300 IPPS hospitals) at a cost of $11,275 (275 hours × $41).

c. Information Collection Burden Estimate for the Voluntary Reporting Period and Subsequent Required Submission of the Hybrid Hospital-Wide Mortality Measure With Claims and Electronic Health Record Data

In section IX.C.5.b. of the preamble of this final rule, as proposed, we are finalizing to establish a voluntary reporting period for the Hybrid Hospital-Wide Mortality Measure with Claims and Electronic Health Record Data (NQF #3502) (Hybrid HWM measure). The voluntary reporting period would run from July 1, 2022 through June 30, 2023. We also are finalizing our proposal as proposed to require reporting of the Hybrid HWM measure beginning with the reporting period which would run from July 1, 2023 through June 30, 2024 affecting the FY 2026 payment determination and for subsequent years.

As a hybrid measure, this measure uses both claims-based data and EHR data, specifically, a set of core clinical data elements consisting of vital signs and laboratory test information and patient linking variables collected from hospitals' EHR systems. We do not expect any additional burden to hospitals to report the claims-based portion of this measure because these data are already reported to the Medicare program for payment purposes.

However, we do expect that hospitals would experience burden in reporting the EHR data. To report the EHR data, hospitals would use the same submission process as finalized in the FY 2020 IPPS/LTCH PPS final rule for reporting the Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and EHR Data (NQF #2879) (Hybrid HWR measure) (84 FR 42505 through 42508). We expect the burden associated with reporting of the Hybrid HWM measure to be similar to our estimates for reporting the Hybrid HWR measure, that is, 10 minutes per measure, per quarter. Therefore, using the estimate of 10 minutes per measure per quarter (10 minutes × one measure × four quarters = 40 minutes), we estimate that this finalized hybrid measure will result in a burden increase of 40 minutes (0.67 hours) per hospital per year.

In summary, beginning with the voluntary reporting period, which runs from July 1, 2022 through June 30, 2023, we estimate an annual burden increase of 2,200 hours across participating IPPS hospitals (0.67 hours × 3,300 IPPS hospitals). Using the updated wage estimate, as previously described, we estimate this to represent a cost increase of $90,200 across IPPS hospitals ($41 × 2,200 hours). As we are finalizing our proposal to adopt the Hybrid HWM measure, we encourage all hospitals to submit data for the Hybrid HWM measure during the voluntary reporting period. For that reason, our burden estimates assume that all hospitals will participate during the voluntary reporting period (July 1, 2022 through June 30, 2023) as well as for the required reporting period (July 1, 2023 through June 30, 2024) and subsequent reporting periods for which public reporting would begin. Due to the voluntary reporting period beginning in the third quarter of the CY 2022 reporting period/FY 2024 payment determination, the total burden for the first year assumes only two quarters of reporting and is estimated to be 1,100 hours (0.33 hours × 3,300 IPPS hospitals) at a cost of $45,100 ($41 × 1,100 hours). Beginning with the CY 2023 reporting period/FY 2025 payment determination, the total burden estimate will be based on four quarters of reporting.

d. Information Collection Burden Estimate for the Adoption of Two Hospital Harm eCQMs Beginning With the CY 2022 Reporting Period/FY 2024 Payment Determination and Removal of Three eCQMs Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section IX.C.5.d. of the preamble of this final rule, as proposed, we are finalizing to adopt two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: (1) Hospital Harm—Severe Hyperglycemia eCQM; and (2) Hospital Harm—Severe Hypoglycemia eCQM. Also, in section IX.C.6. of this final rule, we are finalizing three of the four proposals as proposed to remove eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination: (1) Admit Decision Time to ED Departure Time for Admitted Patients (ED–2); (2) Exclusive Breast Milk Feeding (PC–05); and (3) Discharged on Statin Medication (STK–06) eCQMs. We are not finalizing the removal of the Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03). We do not believe that finalizing our proposals to add two eCQMs and remove three

[1383] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Accessed on February 18, 2021; available at: *https://www.bls.gov/oes/2019/may/oes292098.htm.*

eCQMS from the eCQM measure set, nor retaining the STK–03 eCQM, will affect the information collection burden of submitting eCQMs under the Hospital IQR Program. Current Hospital IQR Program policy requires hospitals to select four eCQMs from the eCQM measure set on which to report (84 FR 42503 through 4250). In other words, while these provisions will result in new eCQMs being added to and some eCQMs being removed from the eCQM measure set, hospitals will not be required to report more than a total of four eCQMs as is currently required (84 FR 42603).

Specifically, we finalized in the FY 2020 IPPS/LTCH PPS final rule that, for the CY 2021 reporting period/FY 2023 payment determination, hospitals are required to submit data for four self-selected eCQMs each year (84 FR 42503). Additionally, for the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to submit data for three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM for a total of four eCQMs (84 FR 42505). We also finalized a policy to progressively increase the number of quarters of eCQM data reported, from one quarter of data to four quarters of data over a 3-year period beginning with two quarters in the CY 2021 reporting period/FY 2023 payment determination and culminating with four quarters in the CY 2023 reporting period/FY 2025 payment determination (85 FR 59008 through 59009). The newly adopted eCQMs will update the available eCQMs in the eCQM measure set from which hospitals may choose to report to satisfy these requirements. Therefore, we do not expect that finalizing our proposals to adopt and remove these measures or retain one eCQM would impact our information collection burden estimates. However, we refer readers to section I.K. of Appendix A of this final rule for a discussion of the potential costs associated with the implementation and removal of eCQMs which are not strictly related to information collection burden.

e. Information Collection Burden Estimate for Retaining the Death Rate Among Surgical Inpatients With Serious Treatable Complications (CMS PSI–04) Claims-Based Measure Beginning With the FY 2023 Payment Determination

In section IX.C.6.a. of the preamble of this final rule, we are not finalizing our proposal to remove the Death Rate Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) claims-based measure beginning with the CY 2021 reporting period/FY 2023 payment determination. Because CMS PSI–04 is calculated using data that are already reported to the Medicare program for payment purposes, retaining this measure will not result in a change to the burden estimates provided in the FY 2022 IPPS/LTCH proposed rule (86 FR 25686 through 25687).

f. Information Collection Burden Estimate for the Adoption of the COVID–19 Vaccination Coverage Among HCP Measure Beginning With an Interim Reporting Period in CY 2021

In section IX.C.5.c. of the preamble of this final rule, we are finalizing our proposal to adopt a COVID–19 Vaccination Coverage among HCP measure beginning with a shortened reporting period from October 1 to December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination, followed by quarterly reporting periods for the FY 2024 payment determination and for subsequent years. Regarding public reporting of this measure, based on public comment, we are finalizing a modification to our proposal. Under this modification, we will not finalize our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then publicly report the measure using four rolling quarters of data. Instead, we will only publicly report the most recent quarter of data. However, this will not change the information collection burden for hospitals as we are finalizing the data submission requirements as proposed. Hospitals will submit data through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA (OMB control number 0920–1317) because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[1384] As such, this measure will not impose any additional information collection burden for IPPS hospitals for the duration of the PHE. Although the burden associated with the COVID–19 Vaccination Coverage among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666 due to the NCVIA waiver, the estimated cost and burden information is included in the Regulatory Impact Analysis section (Appendix A, section I.K.) of this rule. We will work with CDC to ensure that this burden is accounted for in an updated PRA under OMB control number 0920–1317.

[1384] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

g. Information Collection Burden Estimates for the Adoption of the 2015 Edition Cures Update Criteria for Certified EHR Technology (CEHRT) Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination for eCQMs and Hybrid Measures

In sections IX.C.9.e.2.(a). and IX.C.9.f.2.(b). of the preamble of this final rule, we are finalizing our proposal to require hospitals to use the 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years. Under this policy, hospitals will no longer be able to use the 2015 Edition CEHRT criteria to submit data for the Hospital IQR Program data submission requirements for eCQMs or hybrid measures beginning with the CY 2023 reporting period/FY 2025 payment determination. We do not expect that the finalization of these proposals will affect our information collection burden estimates because this policy does not require hospitals to submit new data to CMS (83 FR 41692). With respect to any costs unrelated to data submission, we refer readers to section I.K. of Appendix A of this final rule.

h. Information Collection Burden Estimate for the Update of References and Code of Federal Regulations Text Relating to QualityNet Security Official

In section IX.C.9.c.(2). of the preamble of this final rule, we are finalizing our proposal to use the term ''QualityNet security official'' instead of ''QualityNet Administrator.'' Specifically, we are finalizing our proposal to revise existing § 412.140(a)(2) by replacing ''QualityNet Administrator'' with ''QualityNet security official'' and § 412.140(e)(2)(iii) by replacing ''QualityNet system administrator'' with ''QualityNet security official.'' We expect that our provision will not yield a change in burden for the hospitals participating in the Hospital IQR Program since the changes only seek to refine regulatory text.

i. Information Collection Burden Estimate for the Update to the References to the QualityNet Website in the Hospital IQR Program Regulation Text

In section IX.C.9.c.(1). of the preamble of this final rule, we are finalizing our proposal to update the references to the QualityNet website from ''*QualityNet.org*'' to ''the QualityNet website'' in the Hospital IQR Program regulation text. Specifically, we are finalizing our proposal to revise existing § 412.140(a)(1) and (c) to remove references to ''*QualityNet.org*'' and replace with ''QualityNet website.'' We expect that our provision will not yield a change in burden for the hospitals participating in the Hospital IQR Program since the changes only seek to refine regulatory text.

j. Information Collection Burden Estimate for the Extension of the Effects of the Educational Review Process for Chart-Abstracted Measures for the FY 2024 Payment Determination and Subsequent Years

In section IX.C.10.b.(1).(b). of the preamble of this final rule, we are finalizing our proposal to extend the educational review policy to use the corrected quarterly score identified through an educational review to compute the final confidence interval for all 4 quarters of validation for chart-abstracted measures. We expect that our policy will not yield a change in burden as it does not affect the requirements for data submission for hospitals, but only modifies how CMS uses the data already being submitted.

k. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022, we estimate that the policies promulgated in this final rule will result in a total increase of 2,475 hours annually for 3,300 IPPS hospitals from the CY 2022 reporting period/FY 2024 payment determination through the CY 2025 reporting period/FY 2027 payment determination. The total cost increase related to this information collection is approximately $101,475 (2,475 hours × $41.00/hour) (which also reflects use of an updated hourly wage rate as previously discussed). The tables summarize the total burden changes for each respective FY payment determination compared to our currently approved information collection burden estimates (the table for the FY 2027 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1022.

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Summary of Hospital IQR Program Information Collection Burden Change for the CY 2022 Reporting Period/FY 2024 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2024 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of IPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across IPPS hospitals**	**Previously finalized annual burden (hours) across IPPS hospitals**	**Net difference in annual burden hours**
Add Maternal Morbidity Structural Measure	5	1	3,300	1	0.083	275	N/A	+275
Add Hybrid Hospital-Wide Mortality Measure	10	2	3,300	1	0.33	+1,100	N/A	+1,100
	Total Change in Information Collection Burden Hours: +1,375							
	Total Cost Estimate: Updated Hourly Wage ($41.00) x Change in Burden Hours (+1,375) = **+$56,375**							

Summary of Annual Hospital IQR Program Information Collection Burden Change for the CY 2023 Reporting Period/FY 2025 Payment Determination through the CY 2025/FY 2027 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2025 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of IPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across IPPS hospitals**	**Previously finalized annual burden (hours) across IPPS hospitals**	**Net difference in annual burden hours**
Add Maternal Morbidity Structural Measure	5	1	3,300	1	0.083	275	N/A	+275
Add Hybrid Hospital-Wide Mortality Measure	10	4	3,300	1	0.67	2,200	N/A	+2,200
	Total Change in Information Collection Burden Hours: +2,475							
	Total Cost Estimate: Updated Hourly Wage ($41.00) x Change in Burden Hours (+2,475) = **+$101,475**							

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7. ICRs for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.D.5. of the preamble of this final rule, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage among HCP measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the FY 2023 program year, followed by quarterly reporting periods (affecting the FY 2024 program year and for subsequent years).[1385] As proposed, PCHs will submit data on the measure through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[1386] Although the burden as associated with the COVID–19 Vaccination Coverage among HCP measure is not currently accounted for under the CDC package approved under OMB control number 0920–1317 or 0920–0666, the estimated cost and burden information is included in the Regulatory Impact Analysis section (see section I.K. of Appendix A of this rule). We will work with CDC to ensure that this burden is accounted for in an updated PRA package prepared by the CDC under OMB control number 0920–1317 after expiration of the waiver.

In section IX.D.4. of the preamble of this final rule, we are finalizing the removal of the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383/PCH–15) measure beginning with the FY 2024 program year. We previously finalized in the FY 2019 IPPPS/LTCH PPS final rule that we would utilize a time estimate of 15 minutes per measure when assessing web-based and/or structural measures (83 FR 41694). As such, we estimated that the removal of this measure from the PCHQR measure set will result in a reduction of 15 minutes (0.25 hours) per PCH per year, with a total annual reduction in reporting burden across all PCHs of 2.75 hours (0.25 hours × 11 PCHs) and a total annual reduction in cost across all PCHs of $113 (2.75 hours × $41.00/hr), beginning with the FY 2024 program year. As previously stated, we are finalizing these provisions as proposed.

We did not receive any comments regarding the ICRs for the PCHQR Program, however, while analyzing them for this final rule, we reviewed the Program's measure set for the FY 2024 program year and concluded that the currently approved burden is overestimated. We included that overestimation in section X.II.B.7. of the proposed rule and are correcting it here.

The overestimation originated in the FY 2019 IPPS/LTCH PPS final rule PRA Supporting Statement A for OMB 0938–1175,[1387] wherein we addressed the incorrect prior inclusion of burden data associated with NHSN measures (which are covered under OMB 0920–0666) and the HCAHPS measure (which is covered under OMB 0938–0981) and updated burden estimates to account for the finalized removal of web-based measures. The FY 2019 IPPS/LTCH PPS final rule PRA Supporting Statement A ultimately overcalculated the number of measures that are not claims-based, and therefore overestimated the burden included in that PRA.

The currently approved burden for the PCHQR Program for the FY 2023 program year is 75,779 hours at a cost of $2,940,225 (75,779 hours × $38.80/hour). As discussed, the currently approved burden hours are incorrectly based on an overestimated assumption of the total number of chart-abstracted measures, structural measures, and measures that utilize a web-based tool. Upon review of the measure set for the PCHQR Program currently approved for the FY 2023 program year, including the eight measures accounted for under OMB control number 0938–1175, the total number of chart-abstracted measures, structural measures, and measures that utilize a web-based tool is 1 (Oncology: Plan of Care for Moderate to Severe Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15)). The other seven measures are claims-based measures. As a result, the currently approved burden estimate should be decreased to 2.75 hours (11 PCHs × 0.25 hours) at a cost of $107 (2.75 hours × $38.80/hr).

As described previously, the removal of the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383/PCH–15) measure beginning with the FY 2024 program year results in a total annual reduction in reporting burden across all PCHs of 2.75 hours (0.25 hours × 11 PCHs) and a total annual reduction in cost across all PCHs of $113 (2.75 hours × $41.00/hr), beginning with the FY 2024 program year. The combination of the correction to currently approved burden estimates and the reduction to burden estimates associated with the measure's removal result in zero hours' reporting burden across all PCHs beginning with the FY 2024 program year.

8. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

The provisions discussed in section IX.E. of this final rule did not impose any new information collection requirements. However, there are references associated with the information collection requirements for the LTCH QRP that are not discussed in the regulation text contained in this document. The following is a discussion of those information collections, some of which have already received OMB approval.

As stated in section IX.E. of the preamble of this final rule, we are finalizing our proposal that LTCHs submit data on one new quality measure: COVID–19 Vaccination Coverage among Healthcare Personnel (HCP). The data source for this quality measure is the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN). LTCHs will submit the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure data to CMS using the NHSN, a web-based tool hosted by the CDC. This reporting service is provided free of charge to LTCHs. LTCHs currently utilize the NHSN for purposes of meeting other LTCH QRP requirements.

We believe that the burden associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP. The burden associated with the COVID–19 Vaccination Coverage among HCP measure is not accounted for under the CDC PRA package currently approved under OMB control number 0920–1317 (expiration 1/31/2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November

[1385] We note that the proposed rule incorrectly read ''annual reporting periods'' however the section of the proposed rule on data submission (IX.D.5.c.) correctly described the data submission process and timelines.

[1386] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[1387] Supporting Statement—Part A Quality Measures and Procedures for the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR Program) for the FY 2021 Program Year, *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201812-0938-018.*

14, 1986 (NCVIA)).[1388] CMS has provided an estimate of the burden and cost to LTCHs, and note that the CDC will include it in a revised information collection request for 0920–1317.

Consistent with the CDC's experience of collecting data using the NHSN, we estimate that it would take each LTCH an average of 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. We believe it will take an administrative assistant from 45 minutes up to 1 hour and 15 minutes to enter this data into NHSN. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates. To account for overhead and fringe benefits, we have doubled the hourly wage.

Based on the time range, it would cost each LTCH between $27.47 and $45.78 per hour each month or an average cost of $36.62 each month, and between $329.64 and $549.36 each year, or an average cost of $439.44 each year. We believe the data submission for the COVID–19 Vaccination Coverage among HCP would cause LTCHs to incur additional average burden of 12 hours per year for each LTCH and a total annual burden of 4,608 hours for all LTCHs. The estimated annual cost across all 363 LTCHs in the U.S. for the submission of the COVID–19 Vaccination Coverage among HCP measure would be between $119,659.32 and $199,417.68, and an average of $159,516.72.

We recognize that many LTCHs may also be reporting other COVID–19 data to HHS. However, we believe the benefits of reporting data on the COVID–19 Vaccination Coverage among HCP measure to assess whether LTCHs are taking steps to limit the spread of COVID–19 among HCP, reduce risk of transmission of COVID–19 within their facilities, and to help sustain the ability of LTCHs to continue serving their communities throughout the PHE and beyond outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into CDC/NHSN.

We did not receive any comments on the estimated time to collect and enter data into the NHSN for the COVID–19 Vaccination Coverage among HCP measure, and are finalizing the revisions as proposed.

9. ICRs for the Medicare Promoting Interoperability Program

a. Historical Background

In section IX.F. of the preamble of the proposed rule and this final rule, we discussed several proposals for the Medicare Promoting Interoperability Program. OMB has currently approved 621,318 total burden hours and approximately $61 million under OMB control number 0938–1278, accounting for information collection burden experienced by approximately 3,300 eligible hospitals and CAHs (Medicare-only and dual-eligible) that attest to CMS under the Medicare Promoting Interoperability Program. The collection of information burden analysis in this final rule focuses on eligible hospitals and CAHs that attest to the objectives and measures, and report eCQMs, under the Medicare Promoting Interoperability Program for the reporting period in CY 2022, CY 2023, and CY 2024.

b. Summary of Policies for Eligible Hospitals and CAHs That Attest to CMS Under the Medicare Promoting Interoperability Program for CY 2022

In section IX.F.3.b. of the preamble of this final rule, we are finalizing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) To maintain the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing its available bonus from five points to 10 points for the EHR reporting period in CY 2022; (2) to add a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation, to the HIE objective as an optional alternative to the two existing measures beginning with the EHR reporting period in CY 2022; (3) to require reporting on four of the existing Public Health and Clinical Data Exchange Objective measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting); (4) to add a new measure to the Protect Patient Health Information objective that requires eligible hospitals and CAHs to attest to having completed an annual assessment of the SAFER Guides beginning with EHR reporting period in CY 2022; (5) to remove attestation statements 2 and 3 from the Medicare Promoting Interoperability Program's prevention of information blocking requirement; and (6) to increase the minimum required scoring threshold for the objectives and measures from 50 points to 60 points (out of 100 points) in order to be considered a meaningful EHR user. We are not finalizing the proposed change to the Provide Patients Electronic Access to Their Health Information Measure (specifically, a proposal to establish a data availability requirement). We are amending the regulations as necessary to incorporate these final policies.

c. Summary of Policies for Eligible Hospitals and CAHs That Attest to CMS Under the Medicare Promoting Interoperability Program for CY 2023

In section IX.F.3.b. of the preamble of this final rule, we are finalizing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 90-day period in CY 2023 for new and returning participants (eligible hospitals and CAHs); and (2) to adopt two new eCQMs to the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2023, which is in alignment with the provisions under the Hospital IQR Program as discussed in section IX.C. of the preamble of this final rule. We are amending the regulations as necessary to incorporate these final policies.

d. Summary of Policies for Eligible Hospitals and CAHs That Attest to CMS Under the Medicare Promoting Interoperability Program for CY 2024

As discussed in section IX.F.3.b. of the preamble of this final rule, we are finalizing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 180-day period in CY 2024 for new and returning participants (eligible hospitals and CAHs); and (2) to remove three eCQMs from the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2024, which is in alignment with the provisions under the Hospital IQR Program as discussed in section IX.C. We are amending the regulations as necessary to incorporate these final policies.

[1388] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

e. Summary of Collection of Information Burden Estimates

(1) Summary of Estimates Used To Calculate the Collection of Information Burden

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated it will take an individual provider or designee approximately 10 minutes to attest to each objective and associated measure that requires a numerator and denominator to be generated. The measures that require a ''yes/no'' response will take approximately 1 minute to complete. We estimated that the Security Risk Analysis measure will take approximately 6 hours for an individual provider or designee to complete (we note this measure is still part of the program, but is not subject to performance-based scoring).

For this final rule, we are finalizing two proposed measure changes which lead to an increase in overall burden to the Medicare Promoting Interoperability Program. First is the updated requirement for the Public Health and Clinical Data Exchange Objective which increases the total number of measures which must be reported from two to four. For the CY 2021 EHR reporting period, the estimated burden associated with reporting on this Objective was one minute, therefore by doubling the number of required measures from two to four, we are estimating the time for CY 2022 reporting would be 2 minutes (or an increase in 0.03 hours per reporting hospital). Although the Objective's Syndromic Surveillance Reporting measure is changing its setting for which data are required to be submitted, we do not anticipate the update from ''urgent care'' to ''emergency department'' to change burden hours given that the capacity to submit reports is already an existing part of built-in CEHRT functionality. Secondly, we are finalizing the requirement for a new measure based on SAFER Guides Reporting, which we have anticipated will take 1 minute to report (as it is proposed to be completed via a single yes/no attestation response). The inclusion of reporting on this SAFER Guides measure will increase the total burden by 0.02 hours. Lastly, we are finalizing the proposed inclusion of a new HIE Bi-Directional Exchange measure, which would not have any effect on the estimated reporting burden given that it will be available as an optional, alternative reporting method to the two current Support Electronic Referral Loops measures, therefore resulting in no net change in burden. Providers will only be required to respond with either the two existing measures OR choose the new Bi-Directional Exchange measure, but the amount of associated burden equals the same regardless of their selection and thus does not require any additional change in hours.

As discussed in section IX.F. of this final rule, we are finalizing the proposal to continue the EHR reporting period as any self-selected continuous 90-days in CY 2023 and to increase the EHR reporting period as any self-selected continuous 180-days in CY 2024. We do not anticipate additional burden due to how the QualityNet attestation system (also referred to as the Hospital Quality Reporting system) is setup and operated to account for the estimated time spent with reporting to CMS (submitting automated reports via CEHRT or attesting to the Program's objectives and measures would not be impacted by a longer EHR reporting period). A similar approach applies to the final policy for increasing the scoring threshold from 50 to 60 points, which does not require any expectation that submitting providers would endure a longer time duration of reporting or attesting to the Program (the threshold only indicates the minimum score necessary to be considered a meaningful EHR user). Finally, we do not believe that our provisions aligned with the Hospital IQR Program to add two eCQMs and remove three eCQMs from the eCQM measure set would affect the information collection burden of submitting eCQMs under the Medicare Promoting Interoperability Program. Previously finalized policy requires hospitals to select eCQMs from the eCQM measure set on which to report (85 FR 58970 through 58976). In other words, while these provisions will result in new eCQMs being added to and some eCQMs being removed from the eCQM measure set, hospitals would not be required to report more than a total of four eCQMs as is currently required (85 FR 58970 through 58971). We believe these are appropriate burden estimates for reporting and have used this methodology in our collection of information burden estimates for this final rule.

Given the provisions, we estimate a total burden estimate of 6 hours 33 minutes per respondent (approximately 6.5 hours) which is an increase of 2 minutes from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58432).

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden Per Respondent for CY 2022: § 495.24(e) - Objectives/Measures Medicare (Eligible Hospitals/CAHs)

Objective	Measure	Burden Estimate per Eligible Hospital and CAH
Protect Patient Health Information	Security Risk Analysis	6 hours
	SAFER Guides*	1 minute*
Electronic Prescribing	e-Prescribing Query of PDMP (BONUS)	10 minutes
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information Support Electronic Referral Loops by Receiving and Reconciling Health Information -OR- Health Information Exchange Bi-Directional Exchange *	10 minutes
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	10 minutes
Public Health and Clinical Data Exchange	Report the following 4 measures ● Syndromic Surveillance Reporting ● Immunization Registry Reporting ● Electronic Case Reporting ● Electronic Reportable Laboratory Result Reporting Report one of the following measures (BONUS) • Public Health Registry Reporting ● Clinical Data Registry -Reporting	2 minutes*
Total Burden Estimate per Respondent		6 hours 33 minutes (6.5 hours)

*Indicates a proposed change to the estimated annual information collection burden per respondent.

(2) Hourly Labor Costs

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated a mean hourly rate of $63.46 for the staff involved in attesting to EHR technology, meaningful use objectives and associated measures, and electronically submitting the clinical quality measures. This reflected the mean hourly rate of a lawyer. We had previously used the mean hourly rate of $68.22 for the necessary staff involved in attesting to the objectives and measures under 42 CFR 495.24(e) in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42609). This rate was updated to $69.34 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59014) based upon then recently released 2018 data from the Bureau of Labor Statistics (BLS).[1389]

The Medicare Promoting Interoperability Program has previously utilized this lawyer hourly wage rate; however, we have determined that it is no longer the most accurate professional among the hospital staff members who are most likely to complete the program's required electronic responses and attestations for the Program. Rather, we believe hospital staff similar to the staff who report for the Hospital Inpatient Quality Reporting Program are utilized to report for the Medicare Promoting Interoperability Program, specifically, a medical records and health information technician staffing role. We believe that both current and anticipated labor performed by participating hospitals in order to successfully complete the Program's reporting requirements is accomplished by this technical role and not the position of a lawyer. Therefore, in properly calculating our estimated burden, we replaced the existing lawyer's wage rate of $69.34 with that of a medical records and health information technician's median wage rate ($20.50 according to the 2019 U.S. Bureau of Labor Statistics).[1390] We believe it more accurately reflects the real-world scenario of those staff members performing the required labor.

We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with the Hospital IQR Program. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($20.50 × 2 = $41) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculated cost burden to hospitals using a wage plus benefits estimate of $41 per hour throughout the discussion in this section of this final rule for the Medicare Promoting Interoperability Program.

In summary, we finalized our proposals and estimate a minimal increase in total burden hours for the Medicare Promoting Interoperability Program for CY 2022 (an increase of 2 additional minutes per hospital). Using the median hourly wage for a medical records and health information technician, we estimate a burden cost increase for CY 2022 of $1.37 per hospital. We estimate the total annual burden of 21,450 burden hours across 3,300 responses for the Program's objectives and measures, and we estimate the total burden cost for CY 2022 to be $879,450 (21,450 hours × $41). Given that the total cost estimate for CY 2021 in last year's final rule was $1,487,343, these updates will result in a net cost decrease of $607,893 for the Medicare Promoting Interoperability Program.

We are finalizing our provisions for CY 2023 and CY 2024 as proposed and we do not estimate any net change in total burden hours for the Medicare Promoting Interoperability Program when compared to CY 2022 estimates. CY 2023 provisions only include an extension of the current 90-day EHR reporting period and the adoption of two new eCQMs to the Program's eCQM

[1389] *https://www.bls.gov/oes/current/oes231011.htm.* Accessed April 21, 2021.

[1390] *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm#tab-1.* Accessed on February 21, 2021.

measure set (in alignment with the proposals being finalized under the Hospital IQR Program), whereas CY 2024 provisions include a 180-day EHR reporting period and the removal of three eCQMs from the Program's eCQM measure set (in alignment with proposals being finalized under the Hospital IQR Program). Both provisions for CY 2023 and CY 2024 have already been detailed to create no net change to the total burden hours and therefore we estimate both years as having the same total cost of $879,450 (21,450 hours × $41).

The burden hours associated with reporting program requirements is currently approved under OMB control number 0938–1278. The updated burden cost estimates discussed in this section will be revised and submitted to OMB for final approval.

We did not receive any comments regarding the ICRs for the Medicare Promoting Interoperability Program and are finalizing without modification.

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden (Total Hours and Cost) Finalized for CY 2021

Regulations Section	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
42 CFR 495.24(e)	3,300	3,300	6.5	21,450	69.34	1,487,343

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden (Total Hours and Cost) Proposed for CY 2022 – CY 2024

Regulations Section	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
42 CFR 495.24(e)	3,300	3,300	6.5	21,450	41.00	879,450

10. Summary of All Burden in This Final Rule

The following chart reflects the total burden and associated costs for the provisions included in this final rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Hospital Inpatient Quality Reporting Program	+2,475	$101,475
Hospital Value-Based Purchasing Program	N/A	N/A
HAC Reduction Program	N/A	N/A
Hospital Readmissions Reduction Program[1]	N/A	N/A
Promoting Interoperability Programs [2]	N/A	-$607,893
LTCH Quality Reporting Program	N/A	N/A
PPS-Exempt Cancer Hospital Quality Reporting Program	-3	-$113
TOTAL	**+2,472**	**-506,531**

* Numbers rounded.

[1] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for-service claims that hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

[2] Medicare Promoting Interoperability Program indicates a reduced cost from the previous year due to how the designated role to report on program requirements has been updated to a Medical Records and Health Information Technician which utilizes a lower hourly wage rate.

I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 26, 2021.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, and Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health

professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs-health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services is amending 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for Part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.1 is amended by adding paragraph (a)(7) and revising paragraph (b)(2) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(7) This part implements section 1866(k) of the Act, which directs hospitals described in section 1886(d)(1)(B)(v) of the Act to submit data on quality measures to the Secretary.

(b) * * *

(2) Subpart B of this part sets forth all of the following:

(i)(A) The classifications of hospitals that are included in and excluded from the prospective payment systems specified in paragraph (a)(1) of this section.

(B) Requirements governing the inclusion or exclusion of hospitals in the systems as a result of changes in their classification.

(ii) Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

* * * * *

■ 3. Section 412.23 is amended by adding paragraph (f)(3) to read as follows:

§ 412.23 Excluded Hospitals: Classifications.

* * * * *

(f) * * *

(3) *PCHQR Program.* All hospitals classified as cancer hospitals under this paragraph must comply with the requirements of the PPS-Exempt Cancer Hospital Quality Reporting Program, as described in § 412.24.

* * * * *

■ 4. Section 412.24 is added to read as follows:

§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

(a) *Applicability.* The PCHQR Program applies to hospitals that are classified as cancer hospitals (PCHs) under the criteria described in § 412.23(f)(1) or (2).

(b) *Participation in the PCHQR Program.* In order to participate in the PCHQR Program, a PCH must do both of the following:

(1) Register with QualityNet (*http://qualitynet.cms.gov*) prior to reporting, including designating a QualityNet security official who completes all steps of the PCHQR Program registration process as described on the QualityNet website.

(2) Enroll in CDC's National Healthcare Safety Network (*https://www.cdc.gov/nhsn/enrollment/index.html*).

(c) *Submission of PCHQR Program data.* Except as provided in paragraph (e) of this section, PCHs that participate in the PCHQR Program must submit to CMS data on quality measures specified under section 1833(k)(3) of the Act in a form and manner, and at a time, specified by CMS. PCHs that participate in the PCHQR Program must also submit an annual online Data Accuracy and Completeness Acknowledgement via the Hospital Quality Reporting (HQR) system that attests to the accuracy and completeness of these data by the deadline specified by CMS on the QualityNet website (*http://qualitynet.cms.gov*).

(d) *Quality measure updates, retention, and removal*—(1) *Updating of measure specifications.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the PCHQR Program. CMS announces technical measure specification updates through the QualityNet website (*http://qualitynet.cms.gov*) and listserv announcements.

(2) *Measure retention.* All quality measures specified under section 1866(k)(3) for the PCHQR Program measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(3) *Measure removal factors*—(i) *General rule.* CMS may remove or replace a quality measure based on one or more of the following factors:

(A) *Factor 1.* Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

(B) *Factor 2.* A measure does not align with current clinical guidelines or practice.

(C) *Factor 3.* The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(D) *Factor 4.* Performance or improvement on a measure does not result in better patient outcomes.

(E) *Factor 5.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) *Factor 6.* The collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Exception.* CMS may retain a quality measure that meets one or more of the measure removal factors described in paragraph (d)(3)(i) of this section if the continued collection of data on the quality measure would align with a stated CMS or HHS policy objective, including, but not limited to, an objective to increase the number of quality measures that a PCH can report electronically, or an objective to collect data on the measure in one or more other CMS quality reporting programs.

(e) *Extraordinary circumstances exceptions (ECEs).* (1) CMS may grant an ECE to a PCH that has requested an extension or exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the PCH.

(2) CMS may grant an ECE to one or more PCHs that has not requested an exception if CMS determines that—

(i) An extraordinary circumstance has affected an entire region or locale; or

(ii) A systemic problem with one of CMS' data collection systems has directly affected the ability of the PCH to submit data in accordance with paragraph (c) of this section.

(3) A PCH participating in the PCHQR Program that wishes to request an ECE must submit an ECE request to CMS via the QualityNet website (*https://qualitynet.cms.gov/pch/pchqr/resource*) within 90 days of the date that the extraordinary circumstances occurred, along with the following information:

(i) The PCH's CCN, name, reason for requesting an extension or exception, and evidence of the impact of

extraordinary circumstances, including but not limited to photographs and media articles;

(ii) The date when the PCH will again be able to submit PCHQR Program data and a justification for that proposed date;

(iii) The following contact information for the PCH's CEO and any other designated personnel:

(A) Name.

(B) Email address.

(C) Telephone number.

(D) Physical mailing address (not a post office box); and

(iv) The signature of the PCH's CEO or designee on the ECE request.

(f) *Public reporting of PCHQR Program data.* CMS makes data submitted by PCHs under the PCHQR Program available to the public on the Provider Data Catalog website (*https://data.cms.gov/provider-data/*). Prior to making any such data submitted by a PCH available to the public, CMS gives the PCH an opportunity to review the data via the Hospital Quality Reporting (HQR) system (*https://hqr.cms.gov/hqrng/login*) and announces the timeline for review on the QualityNet website (*http://qualitynet.cms.gov*) and applicable listservs.

■ 5. Section 412.64 is amended—

■ a. In paragraph (e)(1)(ii), by removing the phrase ''paragraph (e)(4) of this section'' and adding in its place the phrase ''paragraphs (e)(4) and (h)(4)(vii) of this section'';

■ b. In paragraph (e)(4) introductory text, by removing the phrase ''and the imputed floor under paragraph (h)(4)'' and adding in its place the phrase ''and, for discharges on or after October 1, 2004, and before October 1, 2018, the imputed floor under paragraph (h)(4)'';

■ c. In paragraph (h)(4) introductory text, by removing the phrase ''October 1, 2018, CMS establishes'' and adding in its place the phrase ''October 1, 2018, and for discharges on or after October 1, 2021, CMS establishes'';

■ d. In paragraph (h)(4)(vi) introductory text, by removing the phrase ''October 1, 2018, the minimum'' and adding in its place the phrase ''October 1, 2018, and for discharges on or after October 1, 2021, the minimum'';

■ e. By adding paragraph (h)(4)(vii); and

■ f. By revising paragraph (h)(5).

The addition and revision read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(h) * * *

(4) * * *

(vii) For discharges on or after October 1, 2021, the minimum wage index computed under this paragraph must not be applied in a budget neutral manner.

(5)(i) For purposes of paragraph (h)(4) of this section, for discharges on or after October 1, 2004 and before October 1, 2018, an all-urban State is a State with no rural areas, as defined in this section, or a State in which there are no hospitals classified as rural. For purposes of this definition, a State with rural areas and with hospitals reclassified as rural under § 412.103 is not an all-urban State.

(ii) For purposes of paragraph (h)(4) of this section, for discharges on or after October 1, 2021, an all-urban State is a State with no rural areas, as defined in this section, or a State in which there are no hospitals classified as rural under section 1886 of the Act. For purposes of this definition, a hospital is classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

* * * * *

■ 6. Section 412.96 is amended by revising paragraphs (c)(1) introductory text, (h)(1), and (i)(1) and (2) to read as follows:

§ 412.96 Special treatment: Referral centers.

* * * * *

(c) * * *

(1) *Case-mix index.* CMS sets forth national and regional case-mix index values in each year's annual notice of prospective payment rates published under § 412.8(b). The methodology CMS uses to calculate these criteria is described in paragraph (h) of this section. The case-mix index value to be used for an individual hospital in the determination of whether it meets the case-mix index criteria is that calculated by CMS from the hospital's own billing records for Medicare discharges as processed by the fiscal intermediary and submitted to CMS. The hospital's case-mix index for discharges (not including discharges from units excluded from the prospective payment system under subpart B of this part) during the same Federal fiscal year used to compute the case mix index values under paragraph (h) of this section must be at least equal to—

* * * * *

(h) * * *

(1) *Updating process.* CMS updates the national and regional case-mix index standards using the best available data from hospitals subject to the prospective payment system for the Federal fiscal year.

* * * * *

(i) * * *

(1) *Updating process.* CMS updates the national and regional number of discharges using the best available data for levels of admissions or discharges or both.

(2) *Source of data.* In making the calculations described in paragraph (i)(1) of this section, CMS uses the best available hospital admissions or discharge data.

* * * * *

■ 7. Section 412.103 is amended by—

■ a. Revising paragraph (g(3);

■ b. Redesignating paragraph (g)(4) as (g)(5); and

■ c. Adding a new paragraph (g)(4).

The revision and addition read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

* * * * *

(g) * * *

(3) *Cancellation of rural reclassification on or after October 1, 2019, and before October 1, 2021.* For all written requests submitted by hospitals on or after October, 1, 2019, and before October 1, 2021, to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of a Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year.

(4) *Cancellation of rural reclassification on or after October 1, 2021.* For all written requests submitted by hospitals on or after October 1, 2021, to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 1 calendar year after the effective date of the rural reclassification and not less than 120 days prior to the end of a Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year.

* * * * *

■ 8. Section 412.106 is amended by revising paragraph (g)(1)(iii)(C)(*8*) and adding paragraph (g)(1)(iii)(C)(*9*) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) * * *

(*8*) For each subsequent fiscal year, for all eligible hospitals, except Indian

Health Service and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the most recent cost reporting year for which audits have been conducted.

(*9*) For fiscal year 2022, for Indian Health Service and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare Supplemental Security Income (SSI) patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

* * * * *

§ 412.140 [Amended]

■ 9. Section 412.140 is amended—

■ a. In paragraph (a)(1), by removing the term ''QualityNet.org'' and adding in its place the terms ''QualityNet website'';

■ b. In paragraph (a)(2), by removing the term ''QualityNet Administrator'' and adding in its place the phrase ''QualityNet security official'';

■ c. In paragraph (c)(2)(i), by removing the term ''QualityNet.org'' and adding in its place the terms ''QualityNet website''; and

■ d. In paragraph (e)(2)(iii), by removing the term ''QualityNet system administrator'' and adding in its place the phrase ''QualityNet security official''.

■ 10. Section 412.154 is amended by revising paragraph (f)(4) to read as follows:

§ 412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

* * * * *

(f) * * *

(4) CMS posts the excess readmission ratios for the applicable conditions for a fiscal year for each applicable hospital on the Hospital Compare website or successor website(s).

§ 412.160 [Amended]

■ 11. Section 412.160 is amended in the introductory text by removing the phrase ''in §§ 412.161 through 412.167'' and adding in its place the phrase ''in §§ 412.161 through 412.168''.

§ 412.163 [Amended]

■ 12. Section 412.163 is amended in paragraph (d) by removing the phrase ''the *Hospital Compare* website'' and adding in its place the phrase ''the *Hospital Compare* website, which can be accessed via the Care Compare website at *https://www.medicare.gov/care-compare/*''.

§ 412.164 [Amended]

■ 13. Section 412.164 is amended in paragraph (b) by removing the phrase ''the *Hospital Compare* website'' and adding in its place the phrase ''the *Hospital Compare* website, which can be accessed via the Care Compare website at *https://www.medicare.gov/care-compare/*''.

§ 412.165 [Amended]

■ 14. Section 412.165 is amended—

■ a. In paragraph (c)(2), by removing ''QualityNet website (*QualityNet.org*)'' and adding in its place ''QualityNet website (*https://qualitynet.cms.gov/*)''; and

■ b. In paragraph (c)(4), by removing ''QualityNet website (see *https://www.qualitynet.org*)'' and adding in its place ''QualityNet website (*https://qualitynet.cms.gov/*).

§ 412.167 [Amended]

■ 15. Section 412.167 is amended in paragraph (b)(5) by removing ''QualityNet System Administrator'' and adding in its place ''QualityNet security official''.

■ 16. Section 412.168 is added to read as follows:

§ 412.168 Special rule for FY 2022.

(a) This section sets forth the scoring and payment methodology for the fiscal year 2022 Hospital VBP Program.

(b) CMS calculates a measure rate for all measures selected under § 412.164(a) for fiscal year 2022 but only applies § 412.165(a) to the measures included in the Clinical Outcomes Domain for that fiscal year, which are the following:

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT–30–AMI).

(2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization (MORT–30–HF).

(3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN (updated cohort)).

(4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30–COPD).

(5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG).

(6) Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP–HIP–KNEE).

(c) CMS calculates a domain score for the measures described in paragraph (b)(1) of this section for hospitals that report the minimum number of measures in the Clinical Outcomes Domain.

(d) CMS does not award a Total Performance Score to any hospital.

(e) The total amount available for value-based incentive payments for fiscal year 2022 is equal to the total amount of base-operating DRG payment reductions for that fiscal year, as estimated by the Secretary.

(f) CMS awards value-based incentive payment percentages (as defined in § 412.160) for all hospitals to ensure that each hospital receives an incentive payment amount equal to the amount of the reduction made to its base-operating DRG payment amounts.

■ 17. Section 412.172 is amended by revising paragraph (f)(4) to read as follows:

§ 412.172 Reporting of hospital specific information.

* * * * *

(f) * * *

(4) CMS posts the total hospital-acquired condition score, the domain score, and the score on each measure for each hospital on the Hospital Compare website or successor website.

* * * * *

■ 18. Section 412.278 is amended by revising the first sentence of paragraph (b)(1) and revising paragraph (f)(2)(ii) to read as follows:

§ 412.278 Administrator's review.

* * * * *

(b) * * *

(1) The hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor, in the manner directed by the Office of the Attorney Advisor. * * *

* * * * *

(f) * * *

(2) * * *

(ii) Not later than 105 days following issuance of the MGCRB decision in the case of review at the discretion of the Administrator, except the Administrator may, at his or her discretion, for good cause shown, toll such 105 days.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 19. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 20. Section 413.20 is amended by revising paragraph (d)(3) to read as follows:

§ 413.20 Financial data and reports.

* * * * *

(d) * * *

(3)(i) The provider must furnish the contractor, upon request, copies of patient service charge schedules and changes thereto as they are put into effect; and

(ii) The contractor evaluates the charge schedules as specified in paragraph (d)(3)(i) of this section to determine the extent to which they may be used for determining program payment.

* * * * *

■ 21. Section 413.24 is amended by revising paragraphs (f)(5)(i) introductory text and (f)(5)(i)(A) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(5) * * *

(i) The provider must accurately complete and submit the required cost reporting forms, including all necessary signatures and supporting documents. For providers claiming costs on their cost reports that are allocated from a home office or chain organization, the Home Office Cost statement must be submitted by the home office or chain organization as set forth in paragraph (f)(5)(i)(E) of this section. A cost report is rejected for lack of supporting documentation if it does not include the following, except as provided in paragraph (f)(5)(i)(E) of this section:

(A) *Teaching hospitals.* For teaching hospitals, effective for cost reporting periods beginning on or after October 1, 2021, the Intern and Resident Information System (IRIS) data which must contain the same total counts of direct GME FTE residents (unweighted and weighted) and IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the provider's cost report.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 22. The authority for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 23. Section 425.600 is amended by—

■ a. Redesignating paragraph (a)(4)(i)(B)(*2*)(*iv)* as paragraph (a)(4)(i)(B)(*2*)(*v*);

■ b. Adding new paragraph (a)(4)(i)(B)(*2*)(*iv*); and

■ c. In paragraph (a)(4)(i)(B)(*3*), removing the phrase ''paragraph (a)(4)(i)(B)(*2*)(*iii*)'' and adding in its place the phrase ''paragraph (a)(4)(i)(B)(*2*)(*v*).''

The addition reads as follows:

§ 425.600 Selection of risk model.

(a) * * *

(4) * * *

(i) * * *

(B) * * *

(*2*) * * *

(*iv*) Exception for ACOs participating in the BASIC track's glide path that elect to maintain their participation level for performance year 2022. Prior to the automatic advancement for performance year 2022, an ACO that is participating in the BASIC track's glide path for performance year 2021 may elect to remain in the same level of the BASIC track's glide path in which it participated during the 2021 performance year, for performance year 2022. For performance year 2023, the ACO is automatically advanced to the level of the BASIC track's glide path to which the ACO would have automatically advanced absent the election to maintain its participation level for performance year 2022 and, if applicable, the election to maintain its participation level for performance year 2021 under paragraph (a)(4)(i)(B)(*2*)(*iii*) of this section, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

* * * * *

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 24. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 25. Section 455.410 is amended by adding paragraph (d) to read as follows:

§ 455.410 Enrollment and screening of providers.

* * * * *

(d) The State Medicaid agency must allow enrollment of all Medicare-enrolled providers and suppliers for purposes of processing claims to determine Medicare cost-sharing (as defined in section 1905(p)(3) of the Act) if the providers or suppliers meet all Federal Medicaid enrollment requirements, including, but not limited to, all applicable provisions of 42 CFR part 455, subparts B and E. This paragraph (d) applies even if the Medicare-enrolled provider or supplier is of a type not recognized by the State Medicaid Agency.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 26. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 27. Section 495.4 is amended by—

■ a. Adding paragraphs (2)(vii) and (viii) and (3)(vii) and (viii) to the definition of ''EHR reporting period for a payment adjustment year''; and

■ b. Revising the introductory text and paragraph (1) of the definition of ''Meaningful EHR user''.

The additions and revisions read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(vii) The following are applicable for 2023:

(A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2024 and 2025 payment adjustment years. For the FY 2024 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2023.

(B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2025 payment adjustment year.

(viii) The following are applicable for 2024:

(A) If an eligible hospital has not successfully demonstrated it is a

meaningful EHR user in a prior year, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2025 and 2026 payment adjustment years. For the FY 2025 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2024.

(B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2026 payment adjustment year.

(3) * * *

(vii) The following are applicable for 2023:

(A) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2023 payment adjustment year.

(B) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2023 payment adjustment year.

(viii) The following are applicable for 2024:

(A) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2024 payment adjustment year.

(B) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2024 payment adjustment year.

* * * * *

Meaningful EHR user means all of the following:

(1) Subject to paragraph (3) of this definition, an EP, eligible hospital or CAH that, for an EHR reporting period for a payment year or payment adjustment year—

(i) Demonstrates in accordance with § 495.40 meaningful use of certified EHR technology by meeting the applicable objectives and associated measures under §§ 495.20, 495.22, 495.24;

(ii) Does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT;

(iii) Engages in activities related to supporting providers with the performance of CEHRT; and

(iv) Successfully reports the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

* * * * *

■ 28. Section 495.24 is amended by—

■ a. Revising paragraphs (e)(1)(i) and (e)(4)(ii);

■ b. Adding paragraph (e)(4)(iv);

■ c. Revising paragraphs (e)(5)(ii)(B), (e)(5)(iii)(B), and (e)(6)(ii) introductory text;

■ d. Adding paragraph (e)(6)(ii)(C);

■ e. In paragraph (e)(7)(ii) introductory text, removing the en dash and adding in its place ''all of the following:'';

■ f. In paragraph (e)(7)(ii)(A), by removing ''; and'' and adding in its place a period;

■ g. In paragraph (e)(7)(ii)(B), by removing the sentence ''This measure is worth up to 40 points beginning in CY 2019.''; and

■ h. Revising paragraphs (e)(8)(ii) introductory text, (e)(8)(ii)(A) and (e)(8)(iii) introductory text, (e)(8)(iii)(A)(*1*) and (*2*), and (e)(8)(iii)(D) and (E).

The revisions and additions read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(e) * * *

(1) * * *

(i) Except as specified in paragraph (e)(2) of this section, eligible hospitals and CAHs must do all of the following as part of meeting the definition of a meaningful EHR user under § 495.4:

(A) Meet all objectives and associated measures of the Stage 3 criteria specified in this paragraph (e).

(B) In 2019, 2020, and 2021, earn a total score of at least 50 points.

(C) In 2022 and subsequent years, earn a total score of at least 60 points.

* * * * *

(4) * * *

(ii) *Measure scoring.* Eligible hospitals and CAHs are required to report on the security risk analysis measure in paragraph (e)(4)(iii) of this section, but no points are available for this measure. In 2022 and subsequent years, eligible hospitals and CAHs are required to report on the SAFER Guides measure in paragraph (e)(4)(iv) of this section, but no points are available for this measure.

* * * * *

(iv) *SAFER Guides measure.* Conduct an annual self- assessment using all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs.

* * * * *

(5) * * *

(ii) * * *

(B) In 2020 and subsequent years, eligible hospitals and CAHs must meet the e-Prescribing measure in paragraph (e)(5)(iii)(A) of this section, and have the option to report on the query of PDMP measure in paragraph (e)(5)(iii)(B) of this section.

(*1*) In 2020 and 2021, the electronic prescribing objective in paragraph (e)(5)(i) of this section is worth up to 15 points.

(*2*) In 2022, the electronic prescribing objective in paragraph (e)(5)(i) of this section is worth up to 20 points.

(iii) * * *

(B) *Query of prescription drug monitoring program (PDMP) measure.* Subject to paragraph (e)(3) of this section, for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law. This measure is worth—

(*1*) 5 bonus points in CYs 2019, 2020, and 2021; and

(*2*) 10 bonus points in CY 2022.

* * * * *

(6) * * *

(ii) *Measures.* For CYs 2019, 2020, and 2021, eligible hospitals and CAHs must meet both of the measures specified in paragraphs (e)(6)(ii)(A) and (B) of this section (each worth up to 20 points). For CY 2022, eligible hospitals and CAHs either must meet both of the measures specified in paragraphs (e)(6)(ii)(A) and (B) of this section (each worth up to 20 points) or must meet the measure specified in paragraph (e)(6)(ii)(C) of this section (worth 40 points).

* * * * *

(C) *Health information exchange (HIE) bi-directional exchange measure.* Subject to paragraph (e)(3) of this section, the eligible hospital or CAH must attest to the following:

(*1*) Participating in an HIE in order to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.

(*2*) Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.

(*3*) Using the functions of CEHRT to support bi-directional exchange with an HIE.

* * * * *

(8) * * *

(ii) *Measures.* For CYs 2019, 2020, and 2021, eligible hospitals and CAHs could receive a total of 10 points for the objective under paragraph (e)(8)(i) of this section. In order to meet the objective under paragraph (e)(8)(i) of this section, an eligible hospital or CAH must meet any two measures specified in paragraphs (e)(8)(ii)(A) through (F) of this section. For CY 2022 and subsequent years, eligible hospitals and CAHs could receive a total of 15 points for the objective under paragraph (e)(8)(i) of this section. In order to meet the objective under paragraph (e)(8)(i) of this section and receive 10 points, an eligible hospital or CAH must meet each of the four measures specified in paragraphs (e)(8)(ii)(A), (B), (C), and (F) of this section. An eligible hospital or CAH receives a bonus of 5 points for this objective if they meet one of the measures specified in paragraph (e)(8)(ii)(D) or (E).

(A) *Syndromic surveillance reporting measure.* For CYs 2019, 2020, and 2021, the eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting. For CY 2022 and subsequent years, the eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an emergency department setting (POS 23).

* * * * *

(iii) *Exclusions in accordance with paragraph (e)(2) of this section.* For CYs 2019, 2020, and 2021, if an exclusion is claimed under paragraphs (e)(8)(iii)(A) through (F) of this section for each of the two measures selected for reporting, the 10 points for the objective specified in paragraph (e)(8)(i) of this section will be redistributed to the provide patients electronic access to their health information measure under paragraph (e)(7)(ii) of this section. For CY 2022 and subsequent years, if an exclusion is claimed under paragraphs (e)(8)(iii)(A) through (F) of this section for each of the four measures required for reporting, the 10 points for the objective specified in paragraph (e)(8)(i) of this section will be redistributed to the provide patients electronic access to their health information measure under paragraph (e)(7)(ii) of this section.

(A) * * *

(*1*) For CYs 2019, 2020 and 2021, does not have an emergency or urgent care department.

(*2*) For CY 2022 and subsequent years, does not have an emergency department.

* * * * *

(D)(*1*) For CYs 2019, 2020, and 2021, any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (e)(8)(ii)(D) of this section if the eligible hospital or CAH:

(*i*) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(*2*) For CY 2022 and subsequent years, the exclusions specified in paragraph (D)(*1*) of this paragraph are no longer available.

(E)(*1*) For CYs 2019, 2020, and 2021, any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (e)(8)(ii)(E) of this section if the eligible hospital or CAH:

(*i*) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(*2*) For CY 2022 and subsequent years, the exclusions specified in paragraph (E)(*1*) of this paragraph are no longer available.

* * * * *

■ 29. Section 495.40 is amended by revising paragraphs (b) introductory text and (b)(2)(i)(I) introductory text and adding paragraph (b)(2)(i)(J) to read as follows:

§ 495.40 Demonstration of meaningful use criteria.

* * * * *

(b) *Demonstration by eligible hospitals and CAHs.* An eligible hospital or CAH must demonstrate that it satisfies each of the applicable objectives and associated measures under § 495.20, § 495.22, or § 495.24; supports health information exchange and the prevention of health information blocking or does not take actions to limit or restrict the compatibility or interoperability of CEHRT, as applicable for the EHR reporting period; and engages in activities related to supporting providers with the performance of CEHRT.

(2) * * *

(i) * * *

(I) Support for health information exchange and the prevention of information blocking. For an EHR reporting period in CYs 2017 through 2021, the eligible hospital or CAH must attest that it—

* * * * *

(J) Actions to limit or restrict the compatibility or interoperability of CEHRT. For an EHR reporting period in CY 2022 and subsequent years, the eligible hospital or CAH must attest that it did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

* * * * *

Dated: July 29, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2021, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2021

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and

Medicare hospital inpatient capital-related costs for FY 2022 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2022. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2021.

In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that will be applicable to Medicare LTCHs for FY 2022.

In general, except for SCHs and MDHs, for FY 2022, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (including, as discussed in section IV.E. of the preamble of this final rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 50205 of the Bipartisan Budget Act of 2018 extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

As discussed in section V.A.2. of the preamble of this final rule, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. In general, Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update. Accordingly, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2022. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2022. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2022. In section V. of this Addendum, we discuss policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2022. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2022

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. In this section, we discuss the factors we are using for determining the prospective payment rates for FY 2022.

In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2022, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section V.A. of the preamble of this final rule for a complete discussion on the FY 2022 inpatient hospital update. The table that follows shows these four scenarios:

FY 2022 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS				
FY 2022	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.675	-0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.025	0	-2.025
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.7	-0.7	-0.7	-0.7
Applicable Percentage Increase Applied to Standardized Amount	**2.00**	**-0.025**	**1.325**	**-0.7**

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user (as defined in section 1886(n)(3) of the Act) and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket update, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674). (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62 percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2020 budget neutrality factor and applying a revised factor.
- A positive adjustment of 0.5 percent in FYs 2019 through 2023 as required under section 414 of the MACRA.
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173 (as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years and section 15003 of Public Law 114–255), are budget neutral as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to the standardized amount to implement in a budget neutral manner the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (as described in section III.N. of the preamble of this final rule).
- As discussed in this section and in section III.2.d of the preamble of this final rule, an adjustment to the standardized amount (using our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act) to continue to implement in a budget neutral manner our transition for hospitals negatively impacted due to changes as a result of the implementation of the revised OMB market labor delineations. We refer reader to section III.A.2 of the preamble of this final rule, for a detailed discussion.
- An adjustment to remove the FY 2021 outlier offset and apply an offset for FY 2022, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2022, consistent with current law, we are applying the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are applying a uniform, national budget neutrality adjustment to the FY 2022 wage index for the rural floor.

For FY 2022, we proposed to not remove the FY 2021 Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and not to apply a new factor. As discussed in the proposed rule, if we removed the prior year's adjustment, we would not satisfy budget neutrality. We

stated that we believed this approach ensures the effects of the reasonable cost based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) are budget neutral as required under section 108 of Public Law 116–94. For a discussion of Stem Cell Acquisition Budget Neutrality Factor, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59032 and 59033). When cost report data regarding reasonable cost of acquisition become available, we intend to consider using that reasonable cost data in future rulemaking for budget neutrality.

Comment: A commenter stated that the budget neutrality factor should be removed for FY 2022 because the availability of reliable cost data on stem cell acquisition costs will be delayed due to the COVID–19 PHE.

Response: We appreciate the commenter's input on the potential impact of the COVID–19 PHE on stem cell acquisition cost data. However, section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) requires that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral, and, as stated above, if we removed the prior year's adjustment we would not satisfy budget neutrality.

After consideration of comments received, we are finalizing our proposal without modification. We are not removing the FY 2021 Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and we are not applying a new factor.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2022, as we proposed, we are rebasing and revising the national labor-related and nonlabor-related shares (based on the 2018-based IPPS market basket discussed in section IV.B.3. of the preamble of this final rule). Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2022, as discussed in section IV.B.3. of the preamble of this final rule, as we proposed, we are using a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, as we proposed, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via the internet on the CMS website.

Comment: Some commenters asserted a calculation error regarding the treatment of transfers in setting the standardized amount in 1983 and that this alleged error impacts the FY 2022 standardized amount. This same commenter questioned if CMS had statutory authority to include transfers in the standardized amount for FY 2022.

Response: We disagree with the commenters. The calculations of the standardized amounts since the inception of the IPPS have proceeded through notice and comment rulemaking, and there have been numerous statutory changes to the standardized amounts in the intervening years since the inception of the IPPS. There is no basis for a change to the standardized amount now in FY2022.

Comment: Some commenters stated that CMS misinterpreted ATRA section 631 recoupment related to FY 2017, and that CMS should apply a MS–DRG documentation and coding positive adjustment of 0.7 percentage points in addition to the 0.5 percentage point adjustment proposed. Some commenters believed that would stop the continuation of a recoupment adjustment that no longer serves any recoupment purpose.

Response: We received similar comments on the ATRA requirements related to FY 2017 in response to prior years' rulemaking, such as the FY 2020 proposed rule, and we refer readers to that response. (84 FR 42057). In addition, we refer readers to section II.C of this final rule for additional discussion.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, as we proposed, we calculated the FY 2022 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, as we proposed, we used the 2018-based IPPS operating and capital market baskets for FY 2022. As discussed in section IV.B. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, as we proposed, we reduced the FY 2022 applicable percentage increase (which for this final rule is based on IGI's second quarter 2021 forecast of the 2018-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this final rule.

Based on IGI's second quarter 2021 forecast of the hospital market basket increase (as discussed in Appendix B of this final rule), the forecast of the hospital market basket increase for FY 2022 for this final rule is 2.7 percent. As discussed earlier, for FY 2022, depending on whether a hospital submits quality data under the rules

established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section V.A. of the preamble of this final rule for a complete discussion on the FY 2022 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that will be applied to update the national standardized amount. The standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2022 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2022 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this final rule.

4. Methodology for Calculation of the Average Standardized Amount

As discussed in section I.F. of the preamble of this final rule, as we proposed, we are finalizing to use alternative data for the FY 2022 ratesetting in situations where the latest data available that would typically be used for the final rule is significantly impacted by the COVID–19 PHE. We refer the reader to section I.F. of the preamble of this final rule for further discussion of this final policy and our analysis of the best available data for purposes of FY 2022 ratesetting. In this section, we discuss the data we are finalizing to use for our FY 2022 ratesetting process for the modeling of payments for the budget neutrality factors and the outlier fixed-loss cost threshold.

- Ordinarily, the best available MedPAR data for our ratesetting process would be the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. For FY 2022, under ordinary circumstances, the best available data to model payments for FY 2022 and calculate the budget neutrality adjustments described in this section would be the FY 2020 MedPAR file (discharges on or after October 1, 2019 through discharges on or before September 30, 2020). However, for the reasons discussed in section I.F. of the preamble this final rule, we are finalizing to use the FY 2019 MedPAR claims data, including for purposes of calculating the budget neutrality adjustments and outlier fixed-loss cost threshold.
- The inpatient Provider Specific File (PSF) is maintained by the Medicare Administrative Contractor and contains information about data specific to the provider that affects computations for the IPPS. Typically, for the IPPS ratesetting, to model payments, we use the most recent available data at the time of the development of the proposed and final rules, which is typically from the December update of the PSF for the proposed rule and the March update of the PSF for the final rule. For example, for the FY 2022 rulemaking, the PSF we would typically use for the FY 2022 proposed rule would be the December 2020 update of the PSF and the PSF we would typically use for the final rule would be the March 2021 update of the PSF. The fields used from the PSF in our ratesetting are listed in the impact file posted with each proposed and final rule, which includes provider-specific information such as CCRs, bed size, and Medicaid utilization ratio. For some IPPS hospitals, the provider data for these fields in the March 2021 update of the PSF may have come from cost reports that ended during the COVID–19 PHE, and therefore we believe these fields may be affected by the PHE. For FY 2022, in general, we are finalizing to use the March 2020 update of the PSF, the latest update of the PSF prior to the PHE, except for those fields on the PSF not affected by the PHE, such as provider-type. For those fields on the PSF that we believe were not impacted by the PHE, as we proposed, we are using the March 2021 update of the PSF for this final rule, consistent with our typical process. In the FY 2022 final rule impact file, we have indicated which PSF update the applicable fields were sourced from.

The methodology we used to calculate the FY 2022 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: Include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this final rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded-cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- As in the past, we adjusted the FY 2022 standardized amount to remove the effects of the FY 2021 geographic reclassifications and outlier payments before applying the FY 2022 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2022 payment policies.
- We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We also remove organ acquisition charges, except for cases that group to MS–DRG 018, from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS. Revenue centers 081X–089X are typically excluded from ratesetting, however, we are not removing revenue center 891 charges from MS–DRG 018 claims during ratesetting, because those revenue 891 charges were included in the relative weight calculation for MS–DRG 018, which is consistent with the policy finalized in FY 2021 final rule (85 FR 58600). We note that a new MedPAR variable for revenue code 891 charges was introduced in April 2020.

• For FY 2022 and subsequent fiscal years, as we proposed, we are removing allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).

• The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/.*

For FY 2022, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59029–59030), as we proposed, we also are including all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act. For the same reasons, as we also proposed, we included all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2022, we are continuing to apply a proxy based on the prior fiscal year hospital readmissions payment adjustment (for FY 2022 this would be FY 2021 final adjustment factors from Table 15 of the FY 2021 IPPS/LTCH PPS final rule) and a proxy based on the prior fiscal year hospital VBP payment adjustment (for FY 2022 this would be FY 2021 final adjustment factors from Table 16B of the FY 2021 IPPS/LTCH PPS final rule) on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, as we proposed, we applied a proxy readmissions payment adjustment factor and a proxy hospital VBP payment adjustment factor from the prior final rule on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2022 (as we did for the last 8 fiscal years), as we proposed, we are including estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as

described by section 1886(r)(2) of the Act. That is, we are considered estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section V.E. of the preamble to this final rule and later in this section, we are continuing to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we included estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section V.E. of the preamble of this final rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, as we proposed, we are continuing to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

- As we proposed, we included an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2022. Similar to FY 2021, we are including this adjustment based on data on the prior year's performance. Payments for hospitals will be estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2022.

- In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges. Specifically, we calculated the transfer-adjusted discharges using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program as discussed in section IV.A.2.b. of the preamble of this final rule.

a. Reclassification and Recalibration of MS–DRG Relative Weights

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.G. of the preamble of this final rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For this FY 2022 final rule, as we proposed, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2021 labor-related share percentages, the FY 2021 relative weights, and the FY 2021 pre-reclassified wage data, and applied the estimated FY 2022 hospital readmissions payment adjustments and estimated FY 2022 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2021 labor-related share percentages, the FY 2022 relative weights, and the FY 2021 pre-reclassified wage data, and applied the estimated FY 2022 hospital readmissions payment adjustments and estimated FY 2022 hospital VBP payment adjustments applied previously. Because this payment simulation uses the FY 2022 relative weights, consistent with our policy in section V.F. of the preamble to this final rule, we applied the finalized adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2022 relative weights, as we proposed, we applied the adjustor for certain MS–DRG 18 cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section V.F. of the preamble of this final rule for a complete discussion on the finalized adjustor for certain cases that group to MS–DRG 018 and to section II.E.2.b. of the preamble of this final rule, for a complete discussion of the finalized adjustment to the FY 2022 relative weights to account for certain cases that group to MS–DRG 018.

Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we proposed, we applied the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2021. Please see the table later in this section setting forth each of the FY 2022 budget neutrality factors.

b. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2022, as we proposed, we are adjusting 100 percent

of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this final rule.

To compute a budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2022 relative weights and the FY 2021 pre-reclassified wage indexes, applied the FY 2021 labor-related share of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the FY 2022 hospital readmissions payment adjustment and the estimated FY 2022 hospital VBP payment adjustment; and
- Aggregate payments using the FY 2022 relative weights and the FY 2022 pre-reclassified wage indexes, applied the labor-related share for FY 2022 of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same FY 2022 hospital readmissions payment adjustments and estimated FY 2022 hospital VBP payment adjustments applied previously.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2021 to FY 2022. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the FY 2022 budget neutrality factors.

c. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, with regard to the requirement under section 1886(d)(8)(C)(iii) of the Act, as finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42333 through 42336), we excluded the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) from the calculation of the wage index for rural areas in the State in which the county is located. We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality adjustment factor for FY 2022, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2022 labor-related share percentage, the FY 2022 relative weights, and the FY 2022 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the estimated FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2022 labor-related share percentage, the FY 2022 relative weights, and the FY 2022 wage data after such reclassifications, and applied the same estimated FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this final rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks for FY 2022, and applies the policies explained in section III. of the preamble of this final rule. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the FY 2022 budget neutrality factors.

The FY 2022 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2021 budget neutrality adjustment factor. We note that the FY 2022 budget neutrality adjustment reflects FY 2022 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this final rule.

As discussed in the preamble of this final rule, we are finalizing the provisions of the May 10, 2021 IFC (''Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board (MGCRB)'' (CMS–1762–IFC)) without modification, including our revisions to the regulations at § 412.230 to allow hospitals with a rural redesignation under section 1886(d)(8)(E) of the Act to reclassify under the MGCRB using the rural reclassified area as the geographic area in which the hospital is located effective with reclassifications beginning with FY 2023. Therefore, we included any amounts hospitals receive by reason of a higher wage index due to the IFC in the calculation of the budget neutrality factor, pursuant to our authority at section 1886(d)(8)(D) and 1886(d)(5)(I)(i). For a complete discussion regarding finalizing the provisions of the May 10, 2021 IFC, we refer the reader to section III.K.3 of this final rule.

d. Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) is equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this final rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index. We note, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42332 through 42336), for FY 2022 we are calculating the rural floor without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103).

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2022, as we proposed, we calculated a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2021 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323).

That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the FY 2022 rural Puerto Rico wage index is calculated based on the average of the FY 2022 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor budget neutrality adjustment factor, we used FY 2019 discharge data to simulate payments, and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the rural floor; and
- National simulated payments with the rural floor.

Based on this comparison, we determined a national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the FY 2022 budget neutrality factors.

As further discussed in section III.G.2 of this final rule, we note that section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021 amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index (or imputed floor) for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Unlike the imputed floor that was in effect from FY 2005 through FY 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In the past, we budget neutralized the estimated increase in payments each year resulting from the imputed floor that was in effect from FY 2005 through FY 2018. For FY 2022 and subsequent years, in applying the imputed floor required under section 1886(d)(3)(E)(iv) of the Act, we are applying the imputed floor after the application of the rural floor and will apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. As noted in section III.G.2 of the propose rule, given the recent enactment of section 9831 of Public Law 117–2 on March 11, 2021, there was not sufficient time available to incorporate the changes required by this statutory provision (which provides for the application of the imputed floor adjustment in a non-budget neutral manner beginning in FY 2022) into the calculation of the provider wage index for this final rule. In this final rule, we have included the imputed floor adjustment in the calculation of the provider wage index in the FY 2022 final rule. We refer the reader to section III.G.2 of the preamble of this final rule for a complete discussion regarding the imputed floor.

e. Rural Community Hospital Demonstration Program Adjustment

In section V.K. of the preamble of this final rule, we discuss the Rural Community Hospital Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed later in this section). We make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. Finally, Division CC, section 128(a) of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) again amended section 410A to require a 15-year extension period in place of the 10-year period. We refer readers to section V.K. of the preamble of this final rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2022, based on the latest data for this final rule, the total amount that we are applying to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $69,577,797. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2022, we computed a factor for the Rural Community Hospital Demonstration budget neutrality adjustment that would be applied to the standardized amount. Please see the table later in this section for a summary of the FY 2022 budget neutrality factors. We refer readers to section V.K. of the preamble of this final rule on complete details regarding the calculation of the amount we are applying to make an adjustment to the standardized amounts.

f. Continuation of the Low Wage Index Hospital Policy—Budget Neutrality Adjustment

As discussed in section III.G.3. of the preamble of this final rule, we are continuing the wage index policy finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (the low wage index hospital policy). As discussed in section III.G.3 of this final rule, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act, we are making a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for hospitals with a wage index below the 25th percentile wage index, is implemented in a budget neutral manner.

To calculate this budget neutrality adjustment factor for FY 2022, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2022 labor-related share percentage, the FY 2022 relative weights, and the FY 2022 wage index for each hospital before adjusting the wage indexes under the low wage index hospital policy, and applied the estimated FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section; and
- Aggregate payments using the FY 2022 labor-related share percentage, the FY 2022 relative weights, and the FY

2022 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same estimated FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.

This FY 2022 budget neutrality adjustment factor was applied to the standardized amount.

g. Transition Budget Neutrality Adjustment

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) we adopted the updates set forth in OMB Bulletin No. 18–04 effective October 1, 2020, beginning with the FY 2021 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 18–04, we refer readers to the FY 2021 IPPS/LTCH PPS final rule.

In connection with our adoption in FY 2021 of the updates in OMB Bulletin 18–04, we adopted a policy to place a 5 percent cap, for FY 2021, on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition is set to expire at the end of FY 2021.

In the FY 2022 IPPS/LTCH proposed rule, given the unprecedented nature of the ongoing COVID–19 PHE, we sought comment on whether it would be appropriate to continue to apply a transition to the FY 2022 wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04. In section III.A.2. of the preamble to this final rule, we noted that we received several comments strongly recommending CMS extend a transition policy similar to that implemented in FY 2020 and FY 2021.

After consideration of the comments, we are finalizing to apply an extended transition to the FY 2022 wage index for hospitals. Specifically, for hospitals that received the transition in FY 2021, we are continuing a wage index transition for FY 2022 under which we will apply a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 to mitigate significant negative impacts of, and provide additional time for hospitals to adapt to, the revised OMB delineations. Also, as discussed in the FY 2021 IPPS/LTCH final rule, we believe applying a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year is an appropriate transition as it provides predictability in payment levels from FY 2021 to the upcoming FY 2022 as well as effectively mitigating any significant decreases in the wage index for FY 2022. We refer the reader to section III.A.2. of the preamble to this final rule for a complete discussion on the rationale of this transition.

For FY 2022, after taking into consideration comments received to the proposed rule, we are using our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to apply a budget neutrality adjustment to the standardized amount so that our transition for hospitals receiving this transition is implemented in a budget neutral manner. We refer readers to section III.A.2. of the preamble of this final rule for a complete discussion. To calculate a transition budget neutrality adjustment factor for FY 2022, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments without the 5-percent cap using the FY 2022 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2022 relative weights, the FY 2022 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage; and
- Aggregate payments with the 5-percent cap using the FY 2022 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2022 relative weights, the FY 2022 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the same FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage.

This FY 2022 budget neutrality adjustment factor was applied to the standardized amount. Please see the table later in this section setting forth each of the FY 2022 budget neutrality factors.

We note, Table 2 associated with this final rule, which is available via the internet on the CMS website contains the wage index by provider before and after applying the low wage index hospital policy and the transition.

The following table is a summary of the FY 2022 budget neutrality factors, as discussed in the previous sections.

Summary of FY 2022 Budget Neutrality Factors	
MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.000107
Wage Index Budget Neutrality Factor	1.000712
Reclassification Budget Neutrality Factor	0.986737
*Rural Floor Budget Neutrality Factor	0.992868
Rural Demonstration Budget Neutrality Factor	0.999361
Low Wage Index Hospital Policy Budget Neutrality Factor	0.998035
Transition Budget Neutrality Factor	0.99987

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

In order to facilitate comments on the alternative approach discussed in section I.F. of the FY 2022 IPPS/LTCH proposed rule of using the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting, and which we stated we might consider finalizing for FY 2022 based on consideration of comments received, for the proposed rule, we made available budget neutrality and other ratesetting adjustments calculated under this alternative approach, which can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. For this final rule, as discussed in section I.F. of this FY 2022 IPPS/LTCH final rule, after consideration of the comments we received, we are finalizing as proposed to use alternative data for the FY 2022 ratesetting in situations where the latest data available that would typically be used for the final rule is significantly impacted by the COVID–19 PHE.

h. Adjustment for FY 2022 Required Under Section 414 of Public Law 114–10 (MACRA)

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. (As noted in the FY 2018 IPPS/LTCH PPS proposed and final rules, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted December 13, 2016, reduced the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points.) Therefore, for FY 2022, we are implementing the required +0.5 percent adjustment to the standardized amount. This is a permanent adjustment to the payment rates.

i. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2022 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. As discussed in the next section, for FY 2022, we are incorporating an estimate of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm*.

(1) Methodology To Incorporate an Estimate of Outlier Reconciliation in the FY 2022 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. We have instructed MACs to identify for CMS any instances where: (1) A hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual (available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) for complete details regarding outlier reconciliation. The regulation at § 412.84(m) further states that at the time of any outlier reconciliation under § 412.84(i)(4), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Section 20.1.2.6 of Chapter 3 of the Medicare Claims Processing Manual contains instructions on how to assess the time value of money for reconciled outlier amounts.

If the operating CCR of a hospital subject to outlier reconciliation is lower at cost report settlement compared to the operating CCR used for payment, the hospital will owe CMS money because it received an outlier overpayment at the time of claim payment. Conversely, if the operating CCR increases at cost report settlement compared to the operating CCR used for payment, CMS will owe the hospital money because the hospital outlier payments were underpaid.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42635), we finalized a methodology to incorporate outlier reconciliation in the FY 2020 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the

methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.

(a) Incorporating a Projection of Outlier Payment Reconciliations for the FY 2022 Outlier Threshold Calculation

Based on the methodology finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2022, as we proposed, we are continuing to incorporate outlier reconciliation in the FY 2022 outlier fixed loss cost threshold.

As discussed in the FY 2020 IPPS/LTCH PPS final rule, for FY 2020, we used the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a begin date on or after October 1, 2013, and on or before September 30, 2014), which we believed would provide the most recent and complete available data to project the estimate of outlier reconciliation. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625) for a discussion on the use of the FY 2014 cost report data for purposes of projecting outlier payment reconciliations for the FY 2020 outlier threshold calculation. For FY 2022, we applied the same methodology finalized in FY 2020, using the historical outlier reconciliation amounts from the FY 2015 cost reports (cost reports with a begin date on or after October 1, 2014, and on or before September 30, 2015).

Similar to the FY 2021 methodology, in this final rule, we are determining a projection of outlier payment reconciliations for the FY 2022 outlier threshold calculation, by advancing the methodology by 1 year. Specifically, we are using FY 2016 cost reports (cost reports with a begin date on or after October 1, 2015, and on or before September 30, 2016).

For FY 2022, we proposed to use the same methodology from FY 2020 to incorporate a projection of operating outlier payment reconciliations for the FY 2022 outlier threshold calculation. The following steps are the same as those finalized in the FY 2020 final rule but with updated data for FY 2022:

Step 1.—Use the Federal FY 2016 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude sole community hospitals (SCHs) that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of historical total of operating outlier reconciliation dollars (Worksheet E, Part A, Line 2.01) using the Federal FY 2016 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total Federal operating payments using the Federal FY 2016 cost reports from Step 1. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Line 2 and Line 2.02), and the outlier reconciliation payments (Worksheet E, Part A, Line 2.01). We note that a negative amount on Worksheet E, Part A, Line 2.01 for outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments for FY 2016. This percentage amount would be used to adjust the outlier target for FY 2022 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we proposed to target 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2016 cost reports based on the December 2020 HCRIS extract, because the aggregate outlier reconciliation dollars from Step 2 are negative, we stated we are targeting an amount higher than 5.1 percent for outlier payments for FY 2022 under our proposed methodology.

For the FY 2022 proposed rule, we used the December 2020 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2022 final rule, we proposed to use the latest quarterly HCRIS extract that is publically available at the time of the development of that rule which, for FY 2022, would be the March 2021 extract. Similar to the FY 2021 final rule, we stated that we might also consider the use of more recent data that may become available for purposes of projecting the estimate of operating outlier reconciliation used in the calculation of the final FY 2022 outlier threshold.

In the FY 2022 proposed rule, based on the December 2020 HCRIS, 12 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $12,140,344 (Step 2). The total Federal operating payments based on the December 2020 HCRIS was $88,239,764,644 (Step 3). The ratio (Step 4) is a negative 0.013758 percent, which, when rounded to the second digit, is −0.01 percent. Therefore, for FY 2022, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent-(-.01 percent)].

When the percentage of operating outlier reconciliation dollars to total Federal operating payments rounds to a negative value (that is, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of the Addendum to the proposed rule, we provide the FY 2022 outlier threshold as calculated for the proposed rule both with and without including this proposed percentage estimate of operating outlier reconciliation.

As explained in the FY 2020 IPPS/LTCH PPS final rule, we proposed to continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. In the past, the outlier offset was six decimals because we targeted and set the threshold at 5.1 percent by adjusting the standardized amount by the outlier offset until operating outlier payments divided by total operating Federal payments plus operating outlier payments equaled approximately 5.1 percent (this approximation resulted in an offset beyond three decimals). However, under our methodology, we believe a three decimal offset of 0.949 reflecting 5.1 percent is appropriate rather than the unrounded six decimal offset that we have calculated for prior fiscal years. Specifically, as discussed in section II.A.5. of this Addendum, we proposed to determine an outlier adjustment by applying a factor to the standardized

amount that accounts for the projected proportion of total estimated FY 2022 operating Federal payments paid as outliers. Our proposed modification to the outlier threshold methodology is designed to adjust the total estimated outlier payments for FY 2022 by incorporating the projection of negative outlier reconciliation. That is, under this proposal, total estimated outlier payments for FY 2022 would be the sum of the estimated FY 2022 outlier payments based on the claims data from the outlier model and the estimated FY 2022 total operating outlier reconciliation dollars. We stated that we believe the proposed methodology would more accurately estimate the outlier adjustment to the standardized amount by increasing the accuracy of the calculation of the total estimated FY 2022 operating Federal payments paid as outliers. In other words, the net effect of our outlier proposal to incorporate a projection for outlier reconciliation dollars into the threshold methodology would be that FY 2022 outlier payments (which included the proposed estimated recoupment percentage for FY 2022 of 0.01 percent) would be 5.1 percent of total operating Federal payments plus total outlier payments. Therefore, the proposed operating outlier offset to the standardized amount was 0.949 (1–0.051).

We invited public comment on our proposed methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed-loss cost outlier threshold for FY 2022.

Comment: A commenter supported incorporating an estimate of outlier reconciliation. A commenter stated that they were successful in replicating the proposed calculations.

Response: We thank the commenter for their feedback on the proposed calculation methodology.

After consideration of the comments received, and for the reasons discussed in the proposed rule and in this final rule, we are finalizing the methodology described previously for incorporating the outlier reconciliation in the outlier threshold calculation. Therefore, for this final rule we used the same steps described previously and in the proposed rule to incorporate a projection of operating outlier payment reconciliations for the calculation of the FY 2022 outlier threshold calculation. The March 2021 HCRIS contained data for 20 hospitals. As stated previously, while we proposed to use the March 2021 HCRIS extract to calculate the reconciliation adjustment for this FY 2022 IPPS final rule, we also stated that similar to the FY 2021 final rule, we might consider the use of more recent data that may become available for purpose of projecting the estimate of operating outlier reconciliation used in the calculation of the final FY 2022 outlier threshold. Data for 4 additional outlier reconciliations were made available to CMS outside of the March 2021 HCRIS update. Similar to our discussion of the estimated operating outlier reconciliation for FY 2021 in the FY 2021 IPPS/LTCH final rule (85 FR 59036), we believe supplementing with 4 hospitals' outlier reconciliation data will lend additional accuracy to project the estimate of operating outlier reconciliation used in the calculation of the outlier threshold. Therefore, in order to use the most complete data for FY 2016 cost reports, we are using the March 2021 HCRIS extract, supplemented by these 4 additional hospitals' data for this FY 2022 IPPS final rule. Without the 4 additional hospitals' data, the rounded operating outlier reconciliation percentage would have been 0.02 (unrounded of 0.02196). As we gain more experience with this policy, we also are considering adding additional lines to the cost report in order to ensure we capture the maximum cost report data with the March HCRIS extract to calculate the percentage adjustment for outlier reconciliation for the final rule for future rulemaking, as we generally expect historical cost reports for the applicable fiscal year to be available by March. Based on March 2021 HCRIS and supplemental data for 4 hospitals, a total of 2 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $19,370,904 (Step 2). The total Federal operating payments based on the March 2021 HCRIS and supplemental 4 reports is $88,220,077,932 (Step 3). The ratio (Step 4) is a negative 0.02196 percent, which, when rounded to the second digit, is negative 0.02 percent. Therefore, for FY 2022, using the finalized methodology, we incorporated a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.12 percent [5.1 percent − (− 0.02 percent)]. As noted previously, when the percentage of operating outlier reconciliation dollars to total Federal operating payments is negative (such is the case when the aggregate amount of outlier reconciliation is negative), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of this Addendum of this final rule, we provide the FY 2022 outlier threshold as calculated both with and without including this percentage estimate of operating outlier reconciliation.

(b) Reduction to the FY 2021 Capital Standard Federal Rate by an Adjustment Factor To Account for the Projected Proportion of Capital IPPS Payments Paid as Outliers

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we proposed to reduce the FY 2022 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement would be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

For FY 2022, we proposed to use the same methodology from FY 2020 to adjust the FY 2022 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. Similar to FY 2020, as part of our proposals for FY 2022 to incorporate into the outlier model the total outlier reconciliation dollars from the most recent and most complete fiscal year cost report data, we also proposed to adjust our estimate of FY 2022 capital outlier payments to incorporate a projection of capital outlier reconciliation payments when determining the adjustment factor to be applied to the capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers. To do so, we proposed to use the following methodology, which generally parallels the methodology to incorporate a projection of operating outlier reconciliation payments for the FY 2022 outlier threshold calculation.

Step 1.—Use the Federal FY 2016 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of

the proposed and final rules, and exclude SCHs that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule. We used the December 2020 HCRIS extract for the proposed rule and stated that we expected to use the March 2020 HCRIS extract for the FY 2022 final rule. Similar to the FY 2020 final rule, we stated that we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2022 adjustment to the FY 2022 capital standard Federal rate.

Step 2.—Calculate the aggregate amount of the historical total of capital outlier reconciliation dollars (Worksheet E, Part A, Line 93, Column 1) using the Federal FY 2016 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total capital Federal payments using the Federal FY 2016 cost reports from Step 1. The total capital Federal payments consist of the capital DRG payments, including capital indirect medical education (IME) and capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation payments (Worksheet E, Part A, Line 93, Column 1). We note that a negative amount on Worksheet E, Part A, Line 93 for capital outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments for FY 2016. This percentage amount would be used to adjust the estimate of capital outlier payments for FY 2022 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, we proposed that the estimate of capital outlier payments for FY 2022 would be determined by adding the percentage in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.) Because the aggregate capital outlier reconciliation dollars from Step 2 are negative, the estimate of capital outlier payments for FY 2022 under our proposed methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

Similarly, for the FY 2022 proposed rule, we used the December 2020 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For this FY 2022 final rule, we proposed to use the latest quarterly HCRIS extract that is publically available at the time of the development of this rule which, for FY 2022, would be the March 2021 extract. As previously noted, we stated that we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2022 adjustment to the FY 2022 capital standard Federal rate.

For the FY 2022 proposed rule, the estimated percentage of FY 2022 capital outlier payments otherwise determined using the shared outlier threshold was 5.34 percent (estimated capital outlier payments of $431,821,043 divided by (estimated capital outlier payments of $431,821,043 plus the estimated total capital Federal payment of $7,651,022,484)). Based on the December 2020 HCRIS, 12 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $915,421 (Step 2). The total Federal capital payments based on the December 2020 HCRIS was $7,961,217,741 (Step 3) which resulted in a ratio (Step 4) of −0.01 percent. Therefore, for FY 2022, taking into account projected capital outlier reconciliation payments under our proposed methodology would decrease the estimated percentage of FY 2022 aggregate capital outlier payments by 0.01 percent.

As discussed in section III.A.2. of this Addendum, we proposed to incorporate the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2022.

We invited public comment on our proposed methodology for projecting an estimate of capital outlier reconciliation and incorporating that estimate into the modeling of the estimate of FY 2022 capital outlier payments for purposes of determining the capital outlier adjustment factor.

We did not receive comments about the proposed capital outlier reconciliation methodology.

For the reasons discussed, we are finalizing the methodology for projecting an estimate of capital outlier reconciliation. Therefore, for this final rule we used the same steps as described in the proposed rule and this final rule to reduce the FY 2022 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers.

For projecting the estimate of capital outlier reconciliation, similar to our projection of the estimate of operating outlier reconciliation, we are using cost report data of 19 hospitals from the March 2021 HCRIS supplemented for 3 hospitals for a total of 22 hospitals, which we believe will lend additional accuracy to the projection of estimated capital outlier reconciliation for FY 2022. Without the 3 additional reports, the step 4 unrounded value for capital outlier reconciliation would have been 0.02, which rounds to 0.02. We note that a difference in the number of cost reports for the operating and capital outlier reconciliation projections is possible and may be due to new hospitals defined in the regulations at

42 CFR 412.300(b) that may receive capital cost-based payments (in lieu of Federal rate payments), and therefore would not receive capital outlier payments. As a result, capital outlier reconciliation is not applicable to such hospitals since there is no capital outlier payment.

The estimated percentage of FY 2022 capital outlier payments otherwise determined using the shared outlier threshold is 5.31 percent (estimated capital outlier payments of $ 430,689,396 divided by (estimated capital outlier payments of $430,689,396 plus the estimated total capital Federal payment of $7,676,990,253)). Based on the March 2021 HCRIS supplemented by the data for 3 additional providers, 22 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $ 1,784,117 (Step 2). The total Federal capital payments based on the March 2021 HCRIS and supplemental 3 reports is approximately $ 7,960,571,775 (Step 3). The ratio (Step 4) is a negative 0.02241 percent, which, when rounded to the second digit, is negative 0.02 percent (Step 4). Therefore, for FY 2022, taking into account projected capital outlier reconciliation payments under our methodology would decrease the estimated percentage of FY 2022 aggregate capital outlier payments by 0.02 percent.

(2) FY 2022 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the FY 2022 outlier threshold, we simulated payments by applying FY 2022 payment rates and policies using cases from the FY 2019 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the proposed FY 2022 outlier threshold, we inflated the charges on the MedPAR claims by 3 years, from FY 2019 to FY 2022. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we proposed to use the following methodology to calculate the charge inflation factor for FY 2022:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of-change in charges per case. We note this is consistent with the methodology used since FY 2014.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS. As noted previously, we are removing allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835–58842).
- Because this payment simulation uses the FY 2022 relative weights, consistent with our policy discussed in section IV.I. of the preamble to this final rule, we applied the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. As discussed in section II.E.2.b. of the preamble of this final rule, we are applying a adjustment to account for certain cases that group to MS–DRG 018 in calculating the FY 2022 relative weights and for purposes of budget neutrality and outlier simulations.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year. However, in the FY 2022 proposed rule, we proposed to use the FY 2019 MedPAR claims data, which is 3 years prior to FY 2022. Therefore, we proposed to inflate the charges on the MedPAR claims data by 3 years.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change. For the same reasons discussed in that rulemaking, and consistent with our proposal to use the FY 2019 MedPAR for purposes of FY 2022 ratesetting, for FY 2022, we proposed to use the same methodology as FY 2020, and based on the same data used in the FY 2021 IPPS/LTCH PPS final rule to determine the charge inflation factor for this final rule. That is, for FY 2022, we proposed to use the MedPAR files for the two most recent available Federal fiscal year time periods prior to the COVID–19 PHE to

calculate the charge inflation factor. Specifically, for the proposed rule we used the March 2019 MedPAR file of FY 2018 (October 1, 2017 to September 30, 2018) charge data (released for the FY 2020 IPPS/LTCH PPS final rule) and the March 2020 MedPAR file of FY 2019 (October 1, 2018 to September 30, 2019) charge data (released for the FY 2021 IPPS/LTCH PPS final rule) to compute the proposed charge inflation factor. We proposed for the FY 2022 IPPS/LTCH PPS final rule to continue to use the charge inflation estimate from the FY 2021 IPPS/LTCH PPS final rule. In addition, we solicited comments on the alternative approach of using the same data we would ordinarily use for purposes of FY 2022 ratesetting, as discussed in section I.F. of this final rule, and noted that under this alternative approach, if finalized, we would anticipate using more recently updated data for purposes of the FY 2022 IPPS/LTCH PPS final rule. Under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case for FY 2022, we compared the average covered charge per case of $61,578.82 ($584,618,863,834/9,493,830 cases) from October 1, 2017 through September 31, 2018, to the average covered charge per case of $65,522.10 ($604,209,834,327/9,221,466 cases) from October 1, 2018 through September 31, 2019. This rate-of-change was 6.4 percent (1.06404) or 20.4 percent over 3 years. Because we proposed to use the FY 2019 MedPAR for the FY 2022 ratesetting, we applied a factor of 20.4 percent (1.20469) over 3 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified previously.

In order to facilitate comments on the alternative approach discussed in section I.F. of the proposed rule and this final rule of using the same data that we would ordinarily use for purposes of FY 2022 ratesetting, and which we stated we may consider finalizing for FY 2022 based on consideration of comments received, we made available budget neutrality and other ratesetting adjustments, including the charge inflation factor, calculated under this alternative approach, which can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We included in a supplemental data file the following: Budget neutrality factors, charge inflation factor, the CCR adjustment factors, and outlier threshold based on this alternative approach. Consistent with historical practice, we stated that if we were to finalize this alternative approach, we would use the most recent available data for the final rule, as appropriate.

As discussed previously, in the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to establish the FY 2022 outlier threshold using hospital CCRs from the March 2020 update to the Provider-Specific File (PSF), which is consistent with our approach of not using data that may have been significantly impacted by the COVID–19 PHE. We proposed to apply the following edits to providers' CCRs in the PSF. We stated that we believe these edits are appropriate in order to accurately model the outlier threshold. We first searched for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replaced these CCRs with the statewide average CCR for the upcoming fiscal year. We also assigned the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We did not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2022, we also proposed to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

In the FY 2022 IPPS/LTCH proposed rule we stated that ordinarily, for the proposed rule, we would use CCRs from the December 2020 update of the PSF and apply an adjustment factor to adjust the CCRs from the December 2020 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2019 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2020 PSF. However, as discussed previously, we believe the operating and capital CCRs in the December 2020 PSF may be significantly impacted by the PHE. Therefore, we proposed to adjust the CCRs from the March 2020 update of the PSF (the latest update of the PSF prior to the PHE) by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2019 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2020 update of the PSF. We noted that we used total transfer-adjusted cases from FY 2019 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison, because this would produce the true percentage change in the average case-weighted operating and capital CCR from 1 year to the next without any effect from a change in case count on different sides of the comparison.

Using this proposed methodology, for the proposed rule, we calculated a March 2019 operating national average case-weighted CCR of 0.254027 and a March 2020 operating national average case-weighted CCR of 0.247548. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2019 operating national average case-weighted CCR from the March 2020 operating national average case-weighted CCR and then dividing the result by the March 2019 national operating average case-weighted CCR. This resulted in a one-year national operating CCR adjustment factor of 0.974495. In the proposed rule, we noted that because we proposed to use CCRs from the March 2020 update of the PSF for FY 2022, we calculated a 2-year national operating CCR adjustment by multiplying 0.974495 * 0.974495.

We used the same proposed methodology to adjust the capital CCRs. Specifically, we calculated a March 2019 capital national average case-weighted CCR of 0.02073 and a March 2020 capital national average case-weighted CCR of 0.019935. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the March 2019 capital national average case-weighted CCR from the March 2020 capital national average case-weighted CCR and then dividing the result by the March 2019 capital national average case-weighted CCR. This resulted in a one-year national capital CCR adjustment factor of 0.96165. In the proposed rule, we noted that because we proposed to use CCRs from the March 2020 update of the PSF for FY 2022, we calculated a 2-year national

capital CCR adjustment by multiplying 0.96165 * 0.96165.

As discussed in section I.F. of the proposed rule and in section I.O of Appendix A of the proposed rule, we solicited comments on an alternative approach of using the same data we would ordinarily use for purposes of FY 2022 ratesetting, which we stated we may consider finalizing for FY 2022 based on consideration of comments received, and made available supplemental data files to facilitate comments on this alternative approach. As noted previously, we included in a supplemental data file the following: Budget neutrality factors, charge inflation factor, the CCR adjustment factors, and outlier threshold based on this alternative approach. Consistent with historical practice, we stated in the proposed rule if we were to finalize this alternative approach, we would use the most recent available data for the final rule, as appropriate.

For purposes of estimating the proposed outlier threshold for FY 2022, we used a wage index that reflects the policies discussed in the proposed rule. This includes the proposed frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act, the proposed out-migration adjustment as added by section 505 of Public Law 108–173, as well as incorporating the FY 2022 wage index adjustment for hospitals with a wage index value below the 25th percentile, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We stated that if we did not take the aforementioned into account, our estimate of total FY 2022 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation). We noted, given the recent enactment of section 9831 of Public Law 117–2 on March 11, 2021, there was not sufficient time available to incorporate the changes required by this statutory provision (which provides for the application of the imputed floor adjustment in a non-budget neutral manner beginning in FY 2022) into the calculation of the provider wage index for the proposed rule. We stated that we will include the imputed floor adjustment in the calculation of the provider wage index in the FY 2022 final rule.

As described in sections V.K. and IV.L., respectively, of the preamble of this final rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We stated in the proposed rule that we do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the outlier threshold calculation or the outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we proposed to exclude the estimated hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.

We noted in the proposed rule that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2022, we proposed to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We stated that we continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we stated that we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2022, we proposed to include estimated FY 2022 uncompensated care payments in the computation of the outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, proposed to incorporate an estimate of FY 2022 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for the FY 2022 proposed rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) was a negative 0.013758 percent, which, when rounded to the second digit, is −0.01 percent. Therefore, for FY 2022, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent-(−.01 percent)]. Under this proposed approach, we determined a proposed threshold of $30,967 and calculated total outlier payments of $5,081,824,613 and total operating Federal payments of $94,365,941,593. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.11 percent target, which reflected our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We noted that, if calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the threshold would be $31,027. We proposed an outlier fixed-loss cost threshold for FY 2022 equal to

the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $30,967. As discussed further in section I.A of this final rule, we noted that the estimate of the proposed outlier threshold using the FY 2020 MedPAR file was $36,483.

Comment: Multiple commenters supported CMS' proposal to continue using claims data and cost report data from prior to the pandemic to set the FY 2022 outlier threshold. Another commenter supported our proposal to use the MedPAR files for the two most recent available Federal fiscal year time periods prior to the COVID–19 PHE to calculate the charge inflation factor and stated that it believes the charge inflation recorded during the PHE is aberrant and, thus, is unlikely to provide a reasonably accurate forecast of charge inflation.

Response: We thank the commenters for their support and are finalizing as proposed to use alternative data for the FY 2022 ratesetting in situations where the latest data available that would typically be used for the final rule is significantly impacted by the COVID–19 PHE.

Comment: Regarding the proposed charge inflation methodology, a commenter stated it supported CMS' proposal to use the pre-PHE data, as it believes the charge inflation recorded during the PHE is aberrant and, thus, is unlikely to provide a reasonably accurate forecast of charge inflation. The commenter believes that CMS' decision to move to publicly available data sets continues to be a thoughtful choice for the Proposed Rule.

The commenter also stated that it believes that CMS should disclose all aspects of its edits to the most current data used for the Proposed Rule and commit to the same process and methods when it recalculates the threshold for purposes of the final rule. Additionally, the commenter stated CMS should commit to make public the data files it uses for the final rule, including all edits and calculations, when it publishes the final rule. A commenter noted that using the FY 2019 data, it calculated a fixed loss threshold of $30,943 versus the published threshold in the proposed rule of $30,967, a difference of $24 or about 0.08%.

Response: We thank the commenter for its input and are finalizing as proposed to use the MedPAR files for the two most recent available Federal fiscal year time periods prior to the COVID–19 PHE to calculate the charge inflation factor. For FY 2022, we have not made any modification to the proposed charge inflation methodology in this final rule. Our inclusion and exclusion criteria of hospitals claims in our measure of charge inflation is discussed above and the claims data we used to measure charge inflation is readily available for the public to replicate the charge inflation factor. In addition, we refer the reader to the detailed discussion in the FY 2020 IPPS/LTCH PPS final rule regarding the use of publicly available data in the charge inflation methodology initially adopted in the FY 2020 IPPS final rule (84 FR 42627).

Finally, the commenter stated that CMS should make public the data files it uses for the final rule, including all edits and calculations, when it publishes the final rule but did not specify which files it was referring to. We believe the data the commenters are requesting is publicly available and, as noted, the commenter indicated it calculated a fixed loss threshold of $30,943, which differed from the published threshold in the proposed rule of $30,967 by $24, or about 0.08%.

Comment: Some commenters requested that CMS consider whether it is appropriate to include extreme cases when calculating the threshold. A commenter explained that high charge cases have a significant impact on the threshold. The commenter stated that it examined the data to understand the factors that drove an increase in the threshold over $5,000 between FY 2017 and FY 2021, and the proposed increase in the threshold by an additional almost $2,000 in FY 2022, and stated that it observed that the inclusion of extreme cases in the calculation of the threshold, the rate of which are increasing over time, significantly impacts CMS' determination of the fixed-loss threshold. If this trend continues (that is, if the number (and proportion) of extreme cases continues to increase each year), the commenter stated that the impact of this population of cases on the threshold will likewise increase. Thus, the commenter recommended that CMS carefully consider what is causing this trend, whether the inclusion of these cases in the calculation of the threshold is appropriate, or whether a separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs. The commenter believes this is consistent with the calculation process used for IPPS rate setting generally, but would also produce a threshold that more accurately reflects the universe of cases. The commenter asserted that a 2013 Office of Inspector General (OIG) Report, Medicare Hospital Outlier Payments Warrant Increased Scrutiny, *https://oig.hhs.gov/oei/reports/oei-06-10-00520.asp*, concurs with this view.

A commenter stated that the calculation of the outlier threshold is flawed considering the changes in payment for new technology and CAR T-cell therapy. The commenter explained that these are high-cost cases that should be removed from the calculation. This commenter concluded that the increase to the threshold will reduce the number of cases that qualify for outlier payment and will result in payments being well below the 5.1 percent outlier target.

Response: As we explained when responding to a similar comment in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38526), the methodology used to calculate the outlier threshold includes all claims in order to account for all different types of cases, including high charge cases, to ensure that CMS meets the 5.1 percent target. As the commenter pointed out, the volume of these cases continues to rise, making their impact on the threshold significant. We believe excluding these cases would artificially lower the threshold. We believe it is important to include all cases in the calculation of the threshold no matter how high or low the charges. Including these cases with high charges lends more accuracy to the threshold, as these cases have an impact on the threshold and continue to rise in volume. Therefore, we believe the inclusion of the high-cost outlier cases in the calculation of the outlier threshold is appropriate.

Also, with regard to the 2013 OIG report that the commenter references, this report studied the distribution of outlier payments and made recommendations based on the OIG findings, but did not mention concerns or make any recommendations with regard to the calculation of the outlier threshold. Therefore, we do not agree with the commenter that the OIG report concurs with its view.

Comment: A commenter stated that it believes that ordinarily it is important to the process for setting the outlier threshold that CMS accurately calculate prior year actual payment comparisons to the 5.1% target. Without doing so, the commenter stated it is impossible for CMS to appropriately modify its methodology to achieve an accurate result. The commenter also noted that CMS' estimates of past outlier payments also routinely exceed the calculations of outlier payments based on HCRIS cost report data. The commenter emphasized the importance of CMS using the most recent data available to more accurately

assess the outlier payment level. The commenter stated that CMS has generally fallen short of its 5.1% outlier target virtually every FY since at least 2013 (the exceptions being meeting it in FY 2019 and exceeding it during the PHE) and yet is still proposing a significant increase in the threshold this year with no rationale offered to explain the prior years' shortfalls in outlier payments.

A commenter noted that in many recent years, the outlier payments have been below the 5.1 percent target, and no adjustments were adopted to make up for the possible outlier payment shortfall in those years. The commenter stated that based on the most recent data, it believes the FY 2022 outlier threshold should be the same amount as in FY 2021, or an amount near $29,064, and reflect at a minimum no increase to the threshold.

Another commenter stated that to the extent an increase in the fixed loss threshold is necessary, it should be limited to the market basket increase.

A commenter noted that, for a given year, typically the final outlier threshold established by CMS in the final rule is lower than the threshold set forth in the proposed rule. The commenter emphasized that CMS should use the most recent data available when the Agency calculates the outlier threshold.

Response: As noted previously, section 1886(d)(5)(A)(iv) of the Act states that outlier payments may not be not less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year. We believe that maintaining the FY 2021 outlier fixed-loss cost threshold for FY 2022 would be inconsistent with the statute because we would be setting a threshold based on the prior fiscal year. Also, when we calculate the threshold, we typically use the updated data that is available at the time of the development of the proposed and final rule. As previously noted, we are finalizing to use alternative data for the FY 2022 ratesetting in situations where the latest data available that would typically be used for the final rule is significantly impacted by the COVID–19 PHE, including for purposes of calculating the FY 2022 outlier threshold.

With regard to the comment that CMS has generally fallen short of its 5.1% outlier target virtually every FY since at least 2013 (the exceptions being meeting it in FY 2019 and exceeding it during the PHE) and yet is still proposing a significant increase in the threshold this year with no rationale offered to explain the prior year shortfalls in payment, as we have previously stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49783), when we conduct our modeling to determine the outlier threshold, we generally factor in all payments and policies that would affect actual payments for the current year in order to estimate that outlier payments are 5.1 percent of total MS–DRG payments. While we recognize that outlier payments have been below the 5.1 percent target in prior fiscal years, we do not believe that these lower payouts are relevant to the current fiscal year because they do not lend greater accuracy to the estimate of payments that are 5.1 percent of total MS–DRG payments for FY 2022. We also note that in response to commenters' concerns, over the years we have modified our outlier threshold calculation by changing the way we adjust the CCRs, changing the measure of inflation and incorporating an adjustment for outlier reconciliation. As in prior years, CMS will continue to consider any suggestions made by the commenters to improve the accuracy of the calculation of the outlier threshold.

Also, CMS' historical policy is to use the best available data when setting the payment rates and factors in both the proposed and final rules. Sometimes there are variables that change between the proposed and final rule as result of the availability of more recent data, such as the charge inflation factor and the CCR adjustment factors that can cause fluctuations in the threshold amount. For FY 2022 we used the same charge inflation factor and CCR adjustment factors as the proposed rule which is based on the data from the FY 2021 IPPS/LTCH final rule. However, other factors such as changes to the wage indexes and market basket applicable percentage increase were updated from FY 2021 to FY 2022 and from the proposed rule to the final rule which can also cause the outlier fixed loss cost threshold to fluctuate.

With regard to the comment that CMS should use the most recent data available when CMS calculates the outlier threshold, as noted above, when we calculate the threshold, we typically use the updated data that is available at the time of the development of the proposed and final rule. As previously noted, we are finalizing to use alternative data for the FY 2022 ratesetting in situations where the latest data available that would typically be used for the final rule is significantly impacted by the COVID–19 PHE, including for purposes of calculating the FY 2022 outlier threshold. We also note that under this finalized policy, the MedPAR data used for this final rule is from the March 2020 update of the FY 2019 MedPAR claims, which is the same update that was used for the proposed rule.

While most of the data and variables for the fixed loss threshold remain the same from the proposed rule to this final rule, we are updating the wage index and other variables such as the applicable percentage increase. The applicable percentage increase may contribute to the slight increase in the final outlier threshold set forth in this final rule $30,988 as compared to the proposed rule $ 30,967. In the proposed rule, the proposed applicable percentage increase was 2.3 percent and in this final rule, the final applicable percentage increase is 2.0 percent. A lower applicable percentage increase typically results in hospitals receiving less Federal payments and more outlier payments per case. Therefore, it seems the lower applicable percentage increases from the proposed rule to the final rule would cause an increase to the fixed-loss outlier threshold so that less cases receive outlier payments to ensure we reach the projected 5.1 percent of total payments. Additionally, changes to the wage index year to year and from the proposed rule to the final rule can impact the fixed-loss outlier threshold.

Comment: A commenter stated that it recognizes that with the release of the MedPAR final data with additional claims, which will lead to new weights being calculated, and with updated cost to charge ratios, it is appropriate to recalculate the fixed loss threshold from the data that will be released with the final rule.

Response: As noted above, when we calculate the threshold, we typically use the updated data that is available at the time of the development of the proposed and final rule. As noted, we are finalizing to use alternative data for the FY 2022 ratesetting in situations where the latest data available that would typically be used for the final rule is significantly impacted by the COVID–19 PHE, including for purposes of the FY 2022 outlier threshold and calculation of the relative weights. Therefore, under this final policy, for FY 2022 we are using the March 2020 update of the FY 2019 MedPAR claims file, as we proposed. Also, we used the updated FY 2022 final rule MS–DRG weights in our calculation of the outlier threshold.

After consideration of the public comments we received, we are using the same methodology we proposed to calculate the final outlier threshold. As discussed previously, we are adopting for this final rule to calculate charge inflation using the publicly available FY

2018 and FY 2019 claims data and to incorporate a projection of outlier payment reconciliations for the FY 2022 outlier threshold calculation. For the FY 2022 final outlier threshold, we used the March 2019 MedPAR file of FY 2018 (October 1, 2017 through September 30, 2018) charge data (released in conjunction with the FY 2020 IPPS/LTCH PPS final rule) and the March 2020 MedPAR file of FY 2019 (October 1, 2018 through September 30, 2019) charge data (released in conjunction with the FY 2021 IPPS/LTCH PPS final rule) to determine the charge inflation factor. To compute the 1 year average annual rate of change in charges per case, we compared the average covered charge per case of $61,578.82 ($584,618,863,834/9,493,830 cases) from October 1, 2017 through September 31, 2018, to the average covered charge per case of $65,522.10 ($604,209,834,327/9,221,466 cases) from October 1, 2018 through September 31, 2019. This rate-of-change was 6.4 percent (1.06404) or 20.4 percent over 3 years. Consistent with using the FY 2019 MedPAR for the FY 2022 ratesetting, as we proposed, we are applying a factor of 20.4 percent over 3 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified previously.

For FY 2022, as we proposed, we are establishing the FY 2022 outlier threshold using hospital CCRs from the March 2020 update to the Provider-Specific File (PSF). We applied the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replaced these CCRs with the statewide average CCR for the upcoming fiscal year. We also assigned the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We did not apply the adjustment factors described below to hospitals assigned the statewide average CCR. For FY 2022, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below).

For this final rule, similar to the approach since FY 2014, we adjusted the CCRs from the March 2020 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2019 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2020 update of the PSF. We note that we used total transfer-adjusted cases from FY 2019 to determine the national average case weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the methodology described previously, for this final rule, we calculated a March 2019 operating national average case-weighted CCR of 0.254027 and a March 2020 operating national average case weighted CCR of 0.247548. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2019 operating national average case-weighted CCR from the March 2020 operating national average case-weighted CCR and then dividing the result by the March 2019 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.974495. As we proposed, because we are using CCRs from the March 2020 update of the PSF for FY 2022, we calculated a two-year proposed national operating CCR adjustment by multiplying 0.974495 * 0.974495.

We used the same methodology to adjust the capital CCRs. Specifically, for this final rule, we calculated a March 2019 capital national average case-weighted CCR of 0.02073 and a March 2020 capital national average case-weighted CCR of 0.019935. We then calculated the percentage change between the two national capital case weighted CCRs by subtracting the March 2019 capital national average case-weighted CCR from the March 2020 capital national average case-weighted CCR and then dividing the result by the March 2019 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.96165. As we proposed, because we are using CCRs from the March 2020 update of the PSF for FY 2022, we calculated a two-year proposed national capital CCR adjustment by multiplying 0.96165 * 0.96165.

As discussed previously, consistent with the proposed rule, for FY 2022, we applied the following policies (as discussed in more detail earlier):

- We used a wage index based on the FY 2022 wage index that hospitals will be paid. This included our policy to remove urban to rural reclassifications from the calculation of the rural floor, applying the imputed floor adjustment, the frontier State floor adjustment in accordance with section 10324(a) of the Affordable Care Act, and the out migration adjustment as added by section 505 of Public Law 108–173, and incorporates our wage index policies to: (1) Increase the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals, and (2) apply a 5 percent cap for FY 2022 for a hospital that was eligible for the 5 percent cap in FY 2021 and who had an additional 5 percent decrease in the hospital's final FY 2022 wage index from the hospital's final wage index in FY 2021. As stated previously, if we did not take the above into account, our estimate of total FY 2022 payments would be too low, and, as a result, our outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.12 percent of total payments (which reflects the estimate of outlier reconciliation calculated for this final rule).
- We excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.
- We used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are finalizing to incorporate an estimate of FY 2022 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for this FY 2022 final rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.021957 percent, which, when rounded to the second digit, is 0.02 percent. Therefore, for FY 2022, we incorporated a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.12 percent [5.1 percent − (0.02 percent)]. Under this approach, we determined a threshold of $30,988 and calculated total outlier payments of $ 5,326,356,951 and total operating

Federal payments of $ 100,164,666,975. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.12 percent target, which reflects our methodology to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying our finalized methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the threshold would have been $31,108. We are finalizing an outlier fixed-loss cost threshold for FY 2022 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any addon payments for new technology, plus $30,988.

Comment: A commenter stated that the COVID–19 PHE increased case acuity and payments increased due to the suspension of the 2% sequestration. Therefore, the commenter recommended that payments should be adjusted from the FY 2022 estimated outlier threshold because of the temporal nature of these additional payments.

Response: We appreciate the commenter's input. The sequestration reduction is a 2-percent reduction to overall payments and is applied after calculating individual payments such as outlier payments. Therefore, CMS has not made any adjustments that consider the 2-percent reduction in our modeling of outlier payments. As a result, no change to the outlier model for FY 2022 is necessary. With regard to the commenter noting the increased case acuity, we refer the reader to section I.F. of this FY 2022 IPPS/LTCH final rule for a discussion of our final policy to use FY 2019 claims in our FY 2022 ratesetting, which applies to modeling of the outlier threshold.

(3) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2022 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) will result in outlier payments that would equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments would equal 5.31 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we are reducing the FY 2022 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the FY 2022 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.947079

*The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2022 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III. A. 2 in the Addendum of this final rule.

We are applying the outlier adjustment factors to the FY 2022 payment rates after removing the effects of the FY 2020 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.142 or capital CCRs greater than 0.135, or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2021 and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable statewide average capital CCRs. As previously stated, the CCRs in Tables 8A and 8B would be used during FY 2022 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation

process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(4) FY 2020 Outlier Payments

Our current estimate, using available FY 2020 claims data, is that actual outlier payments for FY 2020 were approximately 5.47 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2020, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2020. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2020 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2021 period would not be available until after September 30, 2021, we are unable to provide an estimate of actual outlier payments for FY 2021 based on FY 2021 claims data in this final rule. We will provide an estimate of actual FY 2021 outlier payments in the FY 2023 IPPS/LTCH PPS proposed rule.

5. FY 2022 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2022. The standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 67.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we would apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increases for FY 2022.

The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2022 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2021 national standardized amounts to the FY 2022 national standardized amounts. The second through fifth columns display the changes from the FY 2021 standardized amounts for each applicable FY 2022 standardized amount. The first row of the table shows the updated (through FY 2021) average standardized amount after restoring the FY 2021 offsets for outlier payments, geographic reclassification, rural demonstration, lowest quartile, and transition budget neutrality. The MS–DRG reclassification and recalibration, wage index, and stem cell acquisition budget neutrality factors are cumulative. Accordingly, those FY 2021 adjustment factors have not been removed from the base rate in the following table. Additionally, for FY 2022 we have applied the budget neutrality factors for the lowest quartile hospital policy, described previously.

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CHANGES FROM FY 2021 STANDARDIZED AMOUNTS TO THE FY 2022 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2022 Base Rate after removing: 1. FY 2021 Geographic Reclassification Budget Neutrality (0.986616) 2. FY 2021 Operating Outlier Offset (0.949) 3. FY 2021 Rural Demonstration Budget Neutrality Factor (0.999626) 4. FY 2021 Lowest Quartile Budget Neutrality Factor (0.99797) 5. FY 2021 Transition Budget Neutrality Factor (0.998851)	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04
FY 2022 Update Factor	1.02	0.99975	1.01325	0.993
FY 2022 MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.000107	1.000107	1.000107	1.000107
FY 2022 Wage Index Budget Neutrality Factor	1.000712	1.000712	1.000712	1.000712
FY 2022 Reclassification Budget Neutrality Factor	0.986737	0.986737	0.986737	0.986737
FY 2022 Rural Demonstration Budget Neutrality Factor	0.999361	0.999361	0.999361	0.999361
FY 2022 Lowest Quartile Budget Neutrality Factor	0.998035	0.998035	0.998035	0.998035
FY 2022 Transition Budget Neutrality Factor	0.999870	0.999870	0.999870	0.999870
FY 2022 Operating Outlier Factor	0.949	0.949	0.949	0.949
Adjustment for FY 2022 Required under Section 414 of Pub. L. 114-10 (MACRA)	1.005	1.005	1.005	1.005
National Standardized Amount for FY 2022 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (67.6/32.4)	**Labor: $4,138.28 Nonlabor $1,983.43**	**Labor: $4,056.12 Nonlabor: $1,944.05**	**Labor: $4,110.89 Nonlabor: $1,970.30**	**Labor: $4,028.74 Nonlabor: $1,930.93**
National Standardized Amount for FY 2022 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $3,795.46 Nonlabor: $2,326.25**	**Labor: $3,720.11 Nonlabor: $2,280.06**	**Labor: $3,770.34 Nonlabor: $2,310.85**	**Labor: $3,695.00 Nonlabor: $2,264.67**

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B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the labor-related and nonlabor-related shares that we are using to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2022. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2022, as discussed in section IV.B.3. of the preamble of this final rule, we are applying a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this final rule, we discussed the data and methodology for the FY 2022 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described previously. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) website at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/#url=COLA-Rates* to update this nonlabor portion.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51797), we explained that sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. We finalized that, for FY 2012, as OPM transitioned away from COLAs, we would continue to use the same ''frozen'' COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. We refer readers to the FY 2012 IPPS/LTCH PPS final rule for a more detailed discussion of our rationale for continuing to use the frozen COLAs in FY 2012.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), for FY 2013, we continued to use the same COLA factors that were used to adjust payments in FY 2012 (as originally used to adjust payments in FY 2011, which were based on OPM's 2009 COLA factors). We also established a methodology to update the COLA factors published by OPM every 4 years (at the same time as the update of the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28145 and 28146) for a detailed description of this methodology. For FY 2014, we updated the COLA factors for Alaska and Hawaii published by OPM for 2009 using the methodology finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701). In the FY 2018 IPPS/LTCH PPS final rule, we again updated the COLA factors using this same methodology (82 FR 38530).

For FY 2022, we are updating the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Specifically, we are updating the 2009 OPM COLA factors by a comparison of the growth in the Consumer Price Indices (CPIs) for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We note that for the prior update to the COLA factors, we used the growth in the CPI for Anchorage and the CPI for Honolulu. Beginning in 2018, these indexes were renamed to the CPI for Urban Alaska and the CPI for Urban Hawaii due to the BLS updating its sample to reflect the data from the 2010 Decennial Census on the distribution of the urban population (*https://www.bls.gov/regions/west/factsheet/2018cpirevisionwest.pdf,* accessed January 22, 2021). The CPI for Urban Alaska area covers Anchorage and Matanuska-Susitna Borough in the State of Alaska and the CPI for Urban Hawaii covers Honolulu in the State of Hawaii. BLS notes that the indexes are considered continuous over time, regardless of name or composition changes.

Because BLS publishes CPI data for only Urban Alaska and Urban Hawaii, using the methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we are using the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these urban areas and the United States (as measured by the CPIs mentioned previously) are appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the United States.

BLS publishes the CPI for All Items for Urban Alaska, Urban Hawaii, and for the average U.S. city. However, consistent with our methodology finalized in the FY 2013 IPPS/LTCH PPS final rule, we are creating reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share for the 2018-based IPPS market basket is comprised of a different mix of commodities and services. Therefore, we are creating reweighted indexes for Urban Alaska, Urban Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and using the approximate 57 percent commodities/43 percent services shares obtained from the 2018-based IPPS market basket. We created reweighted indexes using BLS data for 2009 through 2020—the most recent data available at the time of this final rulemaking. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530), we created

reweighted indexes based on the 2014-based IPPS market basket (which was adopted for the FY 2018 IPPS update) and BLS data for 2009 through 2016 (the most recent BLS data at the time of the FY 2018 IPPS/LTCH PPS rulemaking).

We continue to believe this methodology is appropriate because we continue to make a COLA for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent. As stated in the FY 2018 IPPS/LTCH PPS final rule ((82 FR 38530), under the COLA update methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating this cap. In applying this finalized methodology for updating the COLA factors, we are continuing to use a cap of 25 percent, as our policy is based on OPM's COLA factors (updated by the methodology described previously).

Applying this methodology, the COLA factors that we are establishing effective for FY 2022 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii are shown in the table in this section. For comparison purposes, we also are showing the COLA factors effective FY 2018 to FY 2021. We note that the COLA factors effective for FY 2022 for City and County of Honolulu, County of Kauai, and County of Maui and County of Kalawao are a result of applying the 25 percent cap as described previously.

Lastly, as we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), we intend to update the COLA factors based on our methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket.

FY 2022 Cost-of-Living Adjustment Factors (COLA): Alaska and Hawaii Hospitals

Area	FY 2018 through FY 2021	FY 2022 through FY 2025
Alaska:		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.25	1.22
Rest of Alaska	1.25	1.24
Hawaii:		
City and County of Honolulu	1.25	1.25
County of Hawaii	1.21	1.22
County of Kauai	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25

We received no comments in response to our discussion of the proposed FY 2022 COLA factors and therefore are finalizing the COLA factors as proposed, effective for FY 2022 .

C. Calculation of the Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2022

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2022 equals the Federal rate (which includes uncompensated care payments).

Under current law, the MDH program has been extended for discharges occurring through September 30, 2022.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section VI.G. of the preamble of this final rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2022 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section. The prospective payment rate for MDHs for FY 2022 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described in this section. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on

whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))

—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)

—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

— Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)

—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount

—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)

—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)

—Operating Outlier Payment = (Operating Costs − Operating Outlier Threshold) × Marginal Cost Factor

—Capital Outlier Payment = (Capital Costs − Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As noted previously, the MDH program has been extended under current law for discharges occurring through September 30, 2022. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2022

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2022	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.675	-0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.025	0	-2.025
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.7	-0.7	-0.7	-0.7
Applicable Percentage Increase Applied to Standardized Amount	**2.0**	**-0.025**	**1.325**	**-0.7**

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section V.B. of the preamble of this final rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH or an MDH is adjusted by the MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. The resulting rate is used in determining the payment rate that an SCH or MDH will receive for its discharges beginning on or after October 1, 2021. We note that, in this final rule, for FY 2022, we are not making a documentation and coding adjustment to the hospital specific-rate. We refer readers to section II.D. of the preamble of this final rule for a complete discussion regarding our policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2022

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we used to determine the capital Federal rate for FY 2022, which would be effective for discharges occurring on or after October 1, 2021.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2022

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2022. In particular, we explain why the FY 2022 capital Federal rate would increase approximately 1.37 percent, compared to the FY 2021 capital Federal rate. As discussed in the impact analysis in Appendix A to this FY 2022 IPPS/LTCH PPS final rule, we estimate that capital payments per discharge will increase approximately 0.9 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

As discussed in section I.F. of the preamble to this final rule, we are finalizing our proposal to use FY 2019 data for the FY 2022 ratesetting in situations where the FY 2020 data were significantly impacted by the COVID–19 PHE. Ordinarily, for this final rule, we would use claims from the FY 2020 MedPAR file for purposes of calculating the budget neutrality adjustment factors for changes resulting from the annual DRG reclassification and recalibration and changes in the GAF. However, as discussed in section I.F. of the preamble to this final rule, we believe the FY 2020 claims data were significantly impacted by the COVID–19 PHE. Therefore, for the purposes of calculating these budget neutrality adjustment factors for FY 2022, we used claims from the March 2020 update of the FY 2019 MedPAR file. Similarly, for this final rule, we ordinarily would use provider data from the March 2021 update of the Provider Specific File (PSF) for purposes of calculating these budget neutrality adjustment factors. However, for some IPPS hospitals, the provider data in the March 2021 update of the PSF may have come from cost reports that ended during the COVID–19 PHE, and therefore we believe these data may be affected by the PHE. Therefore, for the purposes of calculating these budget neutrality adjustment factors for FY 2022, as proposed, we used provider data from the March 2020 update of the PSF, which was derived from cost reports ending prior to the COVID–19 PHE, except for those fields on the PSF not affected by the PHE.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2022 under that framework is 0.8 percent based on a projected 1.1 percent increase in the 2018-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of -0.3 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2022 CIPI projection in that same section of this Addendum. In this final rule, we describe the policy adjustments that we applied in the update framework for FY 2022.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an

equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2022, we projected a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will equal 0.5 percent for FY 2022. The net adjustment for change in case-mix is the difference between the projected real increases in case mix and the projected total increase in case mix. Therefore, the net adjustment for case-mix change in FY 2022 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, for this FY 2022 IPPS/LTCH PPS final rule, we ordinarily would use the FY 2020 MedPAR claims data to evaluate the effects of the FY 2020 DRG reclassification and recalibration. However, for the reasons discussed in section I.F. of the preamble of this final rule, we believe the FY 2020 MedPAR claims data were significantly impacted by the COVID–19 PHE. Due to these impacts, as we proposed, we are not evaluating the effects of the FY 2020 DRG reclassification and recalibration as part of our update for FY 2022. Therefore, as we proposed, we are making a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2022.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of -0.3 percentage point was calculated for the FY 2020 update, for which there are historical data. That is, current historical data indicated that the forecasted FY 2020 CIPI (1.5 percent) used in calculating the FY 2020 update factor was not the same percentage increase as the actual realized price increase (1.2 percent). As this exceeds the 0.25 percentage point threshold, as we proposed, we are making an adjustment of −0.3 percentage point for the forecast error in the update for FY 2022.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this final rule, as we proposed, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2022 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2022, we are using an intensity measure that is based on an average of cost-per-discharge data from the 5-year period beginning with FY 2015 and extending through FY 2019. Based on these data, we estimated that case-mix constant intensity declined during FYs 2015 through 2019. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity would decline during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2022. Therefore, as we proposed, we are making a 0.0 percentage point adjustment for intensity in the update for FY 2022.

Earlier, we described the basis of the components we used to develop the 0.8 percent capital update factor under the capital update framework for FY 2022, as shown in the following table.

FY 2022 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.1
Intensity:	0.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	0.5
Real Across DRG Change	-0.5
Subtotal	0.0
Effect of FY 2020 Reclassification and Recalibration**	0.0
Forecast Error Correction	-0.3
Total Update	0.80

*The capital input price index represents the 2018-based CIPI.

**Due to the impacts of the COVID-19 PHE on the FY 2020 MedPAR claims data, we are not evaluating the effects of the FY 2020 DRG reclassification and recalibration. Therefore, we made a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2022.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2022, we have incorporated the estimated outlier reconciliation payment amounts into the outlier threshold model, as we did for FY 2021. (For more details on our incorporation of the estimated outlier reconciliation payment amounts into the outlier threshold model, please see section II.A. of this Addendum to this final rule.)

For FY 2021, we estimated that outlier payments for capital-related PPS payments would equal 5.34 percent of inpatient capital-related payments based on the capital Federal rate in FY 2021. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs will equal 5.31 percent for inpatient capital-related payments based on the capital Federal rate in FY 2022. However, using the methodology outlined in section II.A. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments will decrease FY 2022 aggregate estimated capital outlier payments by 0.02 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 5.29 percent (5.31 percent − 0.02 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2022. Accordingly, we applied an outlier adjustment factor of 0.9471 in determining the capital Federal rate for FY 2022. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2022 will be lower than the percentage for FY 2021.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The FY 2022 outlier adjustment of 0.9471 is a 0.05 percent change from the FY 2021 outlier adjustment of 0.9466. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2022 is 1.0005 (0.9471/0.9466) so that the outlier adjustment will increase the FY 2022 capital Federal rate by approximately 0.05 percent compared to the FY 2021 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.G.3. of the preamble of this final rule, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to help reduce wage index disparities between high and low wage index hospitals by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index. We stated that this policy will be effective for at least 4 years, beginning in FY 2020. Therefore, as discussed in section III.G.3 of the preamble of this final rule, this policy was applied in FYs 2020 and 2021, and will continue to apply in FY 2022. In FYs 2020 and 2021, we also placed a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year (see (84 FR 42336 through 42338) and (85 FR 58753 through 58755), respectively). As discussed in section III.A.2 of the preamble of this final rule, we solicited comments in the proposed rule on whether it would be appropriate to continue to apply a transition to the FY 2022 wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04. After consideration of comments received, in section III.A.2 of the preamble of this final rule, we are finalizing a policy that for hospitals that received the transition in FY 2021, we are continuing a wage index transition for FY 2022 under which we will apply a 5 percent cap on any decrease in the hospital's wage index compared to its

wage index for FY 2021. Accordingly, our methodology for computing the budget neutrality factor for changes in the GAFs as set forth in this final rule reflects this finalized policy for FY 2022. For this final rule, as noted in the proposed rule, it also reflects the incorporation of imputed floor adjustment.

As we discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42638 through 42639), we augmented our historical methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. Specifically, we established a 2-step methodology, under which we first calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy, consistent with our historical GAF budget neutrality factor methodology. (We note that in FY 2020 we adopted a policy to calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural under § 412.103. We did not change this policy for FY 2022.) In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to our policy to increase the wage index for hospitals with a wage index value below the 25th percentile wage index and our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year in FYs 2020 and 2021. In this section, we refer to these two policies as the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. Although we calculated separate factors for changes to the GAFs under each step of this 2-step methodology, our GAF/DRG budget neutrality factor reflected a single combined GAF budget neutrality factor that accounted for the budget neutrality calculations determined under each step of that methodology.

The budget neutrality factors applied for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are built permanently into the capital Federal rate; that is, they are applied cumulatively in determining the capital Federal rate. In FY 2021, in using the single combined GAF budget neutrality factor that accounted for both steps of our 2-step methodology, we also treated the FY 2020 budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases as a permanent factor and did not remove it from the FY 2021 capital Federal rate. In this final rule, as we proposed, we are no longer permanently applying the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases such that they will not be applied cumulatively in determining the capital Federal rate. We believe this is more technically appropriate because the GAFs with the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policies applied from the previous year are not used in the budget neutrality factor calculations for the current year. These GAFs are not used because the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policies (when applicable) are applied after the imputed floor, out-migration, and frontier state adjustments, which are not subject to budget neutrality. Therefore, in order to continue to exclude the imputed floor, out-migration and frontier state adjustments from budget neutrality, our budget neutrality calculations for permanent factors, as described in more detail later in this section, are determined from aggregate payments calculated using the GAFs from the previous year prior to the application of the imputed floor, out-migration, and frontier state adjustment (and by extension the lowest quartile hospital wage index adjustment and 5-percent cap on wage index decreases). As a result, the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases only ensures budget neutrality for the application of those policies within the year, but not for a change in the policy as compared to the prior year. Accordingly and consistent with this approach, prior to calculating the GAF budget neutrality factors for FY 2022, as we proposed, we removed from the capital Federal rate the cumulative effect of the budget neutrality factor applied in FYs 2020 and 2021 for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. Specifically, we divided the capital Federal rate by a factor of 0.9927, which accounts for the cumulative effect of the FY 2020 budget neutrality factor of 0.9964 (84 FR 42639) and the FY 2021 budget neutrality factor of 0.9963 (85 FR 59047) ($0.9964 \times 0.9963 = 0.9927$).

In light of the changes to the wage index and other wage index policies for FY 2022 discussed previously, which directly affects the GAF, we continue to compute a budget neutrality factor for changes in the GAFs in two steps. We discuss our 2-step calculation of the GAF budget neutrality factors for FY 2022 as follows.

To determine the GAF budget neutrality factors for FY 2022, we first compared estimated aggregate capital Federal rate payments based on the FY 2021 MS–DRG classifications and relative weights and the FY 2021 GAFs to estimated aggregate capital Federal rate payments based on the FY 2021 MS–DRG classifications and relative weights and the FY 2022 GAFs without incorporating the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. To achieve budget neutrality for these changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 1.0003 for FY 2022. Next, we compared estimated aggregate capital Federal rate payments based on the FY 2022 GAFs with and without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. For this calculation, estimated aggregate capital Federal rate payments were calculated using the FY 2022 MS–DRG classifications and relative weights and the FY 2022 GAFs (both with and without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy). (We note, for this calculation the GAFs included the imputed floor, out-migration, and frontier state adjustments.) To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy on the FY 2022 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9974. As discussed earlier in this section, we are finalizing that the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases not be permanently built into the capital Federal rate. Consistent with this policy, and unlike in previous rules, we present the calculated budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases calculated under the second step of this 2-step methodology separately from the other calculated budget neutrality factors in the discussion that follows, and this factor is not included in the calculation of the combined GAF/DRG adjustment factor described later in this section.

We compared estimated aggregate capital Federal rate payments based on the FY 2021 MS–DRG classifications and relative weights and the FY 2022 GAFs (without the lowest quartile

hospital wage index adjustment and the 5-percent cap on wage index decreases) to estimated aggregate capital Federal rate payments based on the FY 2022 MS–DRG classifications and relative weights and the FY 2022 GAFs (without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases). The incremental adjustment factor for DRG classifications and changes in relative weights is 1.0001.

The incremental adjustment factor for MS–DRG classifications and changes in relative weights (1.0001) and for changes in the FY 2022 GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (1.0003) is 1.0004 (1.0001 × 1.0003). This incremental adjustment factor is built permanently into the capital Federal rates. To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy on the FY 2022 GAFs, as described previously, we calculated a budget neutrality adjustment factor of 0.9974 for FY 2022. We refer to this budget neutrality factor for the remainder of this section as the ''Quartile/Cap'' adjustment factor.

We applied the budget neutrality adjustment factors described previously to the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are determined separately. Under the capital IPPS, there is a single budget neutrality adjustment factor for changes in the GAF that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy. In addition, there is no adjustment for the effects that geographic reclassification, the lowest quartile hospital wage index adjustment, or the 5-percent cap on wage index decreases policy described previously have on the other payment parameters, such as the payments for DSH or IME.

The incremental GAF/DRG adjustment factor of 1.0004 accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs that result from updates to the wage data, the effects on the GAFs of FY 2022 geographic reclassification decisions made by the MGCRB compared to FY 2021 decisions, and the application of the rural floor policy. The Quartile/Cap adjustment factor of 0.9974 accounts for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index, and the 5-percent cap on wage index decreases policy. However, these factors do not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Capital Federal Rate for FY 2022

For FY 2021, we established a capital Federal rate of $466.21 (85 FR 59048, as corrected in 85 FR 78756). We are establishing an update of 0.8 percent in determining the FY 2022 capital Federal rate for all hospitals. As a result of this update and the budget neutrality factors discussed earlier, we are establishing a national capital Federal rate of $472.60 for FY 2022. The national capital Federal rate for FY 2022 was calculated as follows:

- The FY 2022 update factor is 1.008; that is, the update is 0.8 percent.
- The FY 2022 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights and changes in the GAFs that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy is 1.0004.
- The FY 2022 Quartile/Cap budget neutrality factor that is applied to the capital Federal rate for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index and the 5-percent cap on wage index decreases policy is 0.9974.
- The FY 2022 outlier adjustment factor is 0.9471.

We are providing the following chart that shows how each of the factors and adjustments for FY 2022 affects the computation of the FY 2022 national capital Federal rate in comparison to the FY 2021 national capital Federal rate. The FY 2022 update factor has the effect of increasing the capital Federal rate by 0.80 percent compared to the FY 2021 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of increasing the capital Federal rate by 0.04 percent. The FY 2022 Quartile/Cap budget neutrality adjustment factor has the effect of increasing the capital Federal rate by 0.47 percent compared to the FY 2021 capital Federal rate. The FY 2022 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.05 percent compared to the FY 2021 capital Federal rate. The combined effect of all the changes would increase the national capital Federal rate by approximately 1.37 percent, compared to the FY 2021 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2021 CAPITAL FEDERAL RATE AND THE FY 2022 CAPITAL FEDERAL RATE

	FY 2021	FY 2022	Change	Percent Change
Update Factor[1]	1.0110	1.0080	1.0080	0.80
GAF/DRG Adjustment Factor[1]	1.0008	1.0004	1.0004	0.04
Quartile/Cap Adjustment Factor[2]	0.9927	0.9974	1.0047	0.47
Outlier Adjustment Factor[3]	0.9466	0.9471	1.0005	0.05
Capital Federal Rate	$466.21	$472.60	1.0137	1.37[4]

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2021 to FY 2022 resulting from the application of the 1.0004 GAF/DRG budget neutrality adjustment factor for FY 2022 is a net change of 1.0004 (or 0.04 percent).

[2] The FY 2021 Quartile/Cap adjustment factor accounts for the cumulative effect of the budget neutrality factors applied in FYs 2020 and 2021 for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. The value was determined as the product of the FY 2020 budget neutrality factor of 0.9964 (84 FR 42639) and the FY 2021 budget neutrality factor of 0.9963 (85 FR 59047). This adjustment factor will not be built permanently into the capital Federal rate; that is, the factor will not be applied cumulatively in determining the capital Federal rate. Therefore, we calculate the net change resulting from the application of the FY 2022 Quartile/Cap adjustment factor as 0.9974/0.9927 or 1.0047 (or 0.47 percent).

[3] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2022 outlier adjustment factor is 0.9471/0.9466 or 1.0005 (or 0.05 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2022

For purposes of calculating payments for each discharge during FY 2022, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier threshold for FY 2022 is in section II.A. of this Addendum. For FY 2022, a case will qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.j. of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the fixed-loss amount of $30,988.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this FY 2022 IPPS/LTCH PPS final rule, we are rebasing and revising the IPPS operating and capital market baskets to reflect a 2018 base year. For a complete discussion of this rebasing, we refer readers to section IV. of the preamble of this final rule.

2. Forecast of the CIPI for FY 2022

Based on IHS Global Inc.'s second quarter 2021 forecast, for this final rule, we are forecasting the 2018-based CIPI to increase 1.1 percent in FY 2022. This reflects a projected 1.7 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.8 percent increase in other capital expense prices in FY 2022, partially offset by a projected 3.2 percent decline in vintage-weighted interest expense prices in FY 2022. The weighted average of these three factors produces the forecasted 1.1 percent increase for the 2018-based CIPI in FY 2022. As proposed, we are using the more recent data available for this final rule to determine the FY 2022 increase in the 2018-based CIPI for the final rule.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2022

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S.

Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of increase limits established under § 413.40 of the regulations.)

As proposed, we are rebasing and revising the IPPS operating basket to a 2018 base year. Therefore, we are using the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2022 and subsequent fiscal years. Accordingly, for FY 2022, the rate-of-increase percentage to be applied to the target amount for these hospitals is the FY 2022 percentage increase in the 2018-based IPPS operating market basket.

For this FY 2022 IPPS/LTCH PPS final rule, based on IGI's 2021 second quarter forecast, we estimate that the 2018-based IPPS operating market basket update for FY 2022 will be 2.7 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2022 rate-of-increase percentage that will be applied to the FY 2021 target amounts in order to calculate the FY 2022 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals will be 2.7 percent, in accordance with the applicable regulations at 42 CFR 413.40.

IRFs and rehabilitation distinct part units, IPFs and psychiatric units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VIII. of the preamble of this final rule and section V. of the Addendum to this final rule for the changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2022. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

V. Changes to the Payment Rates for the LTCH PPS for FY 2022

A. LTCH PPS Standard Federal Payment Rate for FY 2022

1. Overview

In section VIII. of the preamble of this final rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2022.

Under § 412.523(c)(3) of the regulations, for FY 2012 and subsequent years, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II) and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xvii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as discussed in section VIII.C.2 of the preamble of this final rule. This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the FY 2022 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2022, as we proposed, we are applying the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2022, we also are making certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2022 LTCH PPS standard Federal payment rate, as we proposed, we are applying a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data and labor-related share) as discussed in section V.B.5. of this Addendum to this final rule.

In this final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.9 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 2.6 percent less the productivity adjustment of 0.7 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are applying a factor of 1.019 to the FY 2021 LTCH PPS standard Federal payment rate of $ 43,755.34 to determine the FY 2022 LTCH PPS standard Federal payment rate. Also, in accordance with § 412.523(c)(3)(xvii) and § 412.523(c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2022 as required under the LTCH QRP. Therefore, we are establishing an annual update to the LTCH PPS standard Federal payment rate of −0.1 percent (that is, an update factor of 0.999) for FY 2022 for LTCHs that fail to submit the required quality reporting data for FY 2022 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we are applying an area wage level budget neutrality factor to the FY 2022 LTCH PPS standard Federal payment rate of 1.002848, based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index and labor-related share) will not result in any change (increase

or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are establishing an LTCH PPS standard Federal payment rate of $44,713.67 (calculated as $43,755.34 × 1.019 × 1.002848) for FY 2022. For LTCHs that fail to submit quality reporting data for FY 2022, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $43,836.08 (calculated as $43,755.34 × 0.999 × 1.002848) for FY 2022.

B. Adjustment for Area Wage Levels Under the LTCH PPS for FY 2022

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The FY 2022 LTCH PPS standard Federal payment rate wage index values that will be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2021, through September 30, 2022, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website.

2. Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB, and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the Core Based Statistical Areas (CBSAs) established by OMB, which are based on the 2010 decennial census data. In general, the current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013 in OMB Bulletin No. 13–01. (We note we have adopted minor revisions and updates in the years between the decennial censuses.) We adopted these labor market area delineations because they were at that time based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believed that these OMB delineations would ensure that the LTCH PPS area wage level adjustment most appropriately accounted for and reflected the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. OMB Bulletin No. 17–01, issued August 15, 2017, established the delineations for the Nation's statistical areas, and the corresponding changes to the CBSA-based labor market areas were adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731). A copy of this bulletin may be obtained on the website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*. On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. Historically OMB bulletins issued between decennial censuses have only contained minor modifications to CBSA delineations based on changes in population counts. However, OMB's 2010 Standards for Delineating Metropolitan and Micropolitan Standards created a larger mid-decade redelineation that takes into account commuting data from the American Commuting Survey. As a result, the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses. We adopted the updates set forth in OMB Bulletin No. 18–04 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59050 through 59051). A copy of the September 14, 2018 OMB Bulletin No. 18–04, may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04, which was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area and one new component of an existing Combined Statistical Area.

After reviewing OMB Bulletin No. 20–01, we have determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the CBSA-based labor market area delineations used under the LTCH PPS. Specifically, all changes were to New England City and Town Area delineations (NECTA) and the redesignation of a single rural county into a newly created Micropolitan Statistical Area. The LTCH PPS CBSA-based labor market area delineations do not utilize NECTA definitions, and considers hospitals located in Micropolitan Statistical Areas in each State's rural area. Therefore, we are adopting the updates set forth in OMB Bulletin No. 20–01; however, specific wage index updates are not necessary as a result of the adopting the updates.

We believe the CBSA-based labor market area delineations as established in OMB Bulletin 20–01 will ensure that

the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, in this final rule, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are adopting the revisions announced in OMB Bulletin No. 20–01 to the CBSA-based labor market area delineations under the LTCH PPS, effective October 1, 2022. As already noted, our adoption of the updates set forth in OMB Bulletin No. 20–01 will not alter the LTCH PPS area wage level adjustment because our CBSA-based labor market area delineations are the same as the CBSA-based labor market area delineations adopted in the FY 2021 IPPS/LTCH PPS final rule based on OMB Bulletin No. 18–04 (85 FR 59050 through 59051). We also note that, as discussed in section III.A.2. of the preamble of this final rule, we are also using these CBSA-based delineations under the IPPS.

We note that, in connection with our adoption in FY 2021 of the updates in OMB bulletin 18–04, for FY 2021 we adopted a policy to place a 5-percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index in FY 2020, so that an LTCH's wage index for FY 2021 would not be less than 95 percent of its wage index for FY 2020. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59052 through 59053) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition expires at the end of FY 2021.

Comment: We received comments expressing disappointment that CMS did not propose an LTCH wage index transition policy for FY 2022. The commenters cited the severity and continuing impact of changes related to the OMB updates and the unprecedented nature of the ongoing COVID–19 PHE as reasons why CMS should continue to apply a transition policy in FY 2022.

Response: We note that certain changes to wage index policy may significantly affect Medicare payments. These changes may arise from revisions to the OMB delineations of statistical areas resulting from the decennial census data, periodic updates to the OMB delineations in the years between the decennial censuses, or other wage index policy changes. While we consider how best to address these potential scenarios in a consistent and thoughtful manner, we reiterate that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as any approaches to addressing any significant effects on Medicare payments resulting from these potential scenarios, in notice and comment rulemaking.

3. Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH market basket. In addition, for FY 2013 through FY 2016, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) For FY 2017, we rebased and revised the 2009-based LTCH market basket to reflect a 2013 base year. In addition, for FY 2017 through FY 2020, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2013-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57096).) Then, effective for FY 2021, we rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2017 based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).)

In this final rule, consistent with our historical practice, as we proposed, we are establishing that the LTCH PPS labor-related share for FY 2022 is the sum of the FY 2022 relative importance of each labor-related cost category in the LTCH market basket using the most recent available data. Specifically, we are establishing that the labor-related share for FY 2022 includes the sum of the labor-related portion of operating costs from the 2017-based LTCH market basket (that is, the sum of the FY 2022 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the relative importance of Capital-Related cost weight from the 2017-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2017) and FY 2022. Based on IHS Global Inc.'s second quarter 2021 forecast of the 2017-based LTCH market basket, the sum of the FY 2022 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services is 63.6 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (that is, the same percentage applied to the 2009-based and 2013-based LTCH market baskets). Since the FY 2022 relative importance for capital-related costs is 9.3 percent based on IHS Global Inc.'s second quarter 2021 forecast of the 2017-based LTCH market basket, we took 46 percent of 9.3 percent to determine the labor-related share of capital-related costs for FY 2022 of 4.3 percent. Therefore, we are establishing a total labor-related share for FY 2022 of 67.9 percent (the sum of 63.6 percent for the operating cost and 4.3 percent for the labor-related share of capital-related cost).

4. Wage Index for FY 2022 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage

level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 59051 through 59052), we calculated the FY 2021 LTCH PPS area wage index values using the same data used for the FY 2021 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2017), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2021 LTCH PPS area wage index values consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2022 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, as we proposed, we are continuing to employ our historical practice of using the same data we used to compute the FY 2022 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule (that is, wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2018) because these data are the most recent complete data available.

In addition, as we proposed, we computed the FY 2022 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the labor market area delineations as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. As we proposed, we also continued to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values and as we proposed, for FY 2022 we continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2018 IPPS wage data that we used to determine the FY 2022 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the FY 2022 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/wageindex*.

Based on the FY 2018 IPPS wage data that we used to determine the FY 2022 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS standard Federal payment rate wage index value for rural areas with no IPPS wage data for FY 2022. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future.

5. Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2022, in accordance with § 412.523(d)(4), as we proposed, we applied an area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773).

Specifically, as we proposed, we determined an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2022 using the following methodology:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2021 wage index values and the FY 2021 labor-related share of 68.1 percent.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2022 wage index values and the FY 2022 labor-related share of 67.9 percent. (As noted previously, the changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum to this final

rule and the labor-related share is discussed in section V.B.3. of this Addendum to this final rule.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2021 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the FY 2022 updates to the area wage level adjustment (calculated in Step 2) to determine the budget neutrality factor for updates to the area wage level adjustment for FY 2022 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the FY 2022 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2022 LTCH PPS standard Federal payment rate after the application of the FY 2022 annual update.

We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the FY 2022 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor.

For this final rule, using the steps in the methodology previously described, we determined a FY 2022 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.002848. Accordingly, in section V.A. of the Addendum to this final rule, we applied the area wage level adjustment budget neutrality factor of 1.002848 to determine the FY 2022 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we update the COLA factors using the methodology as previously described every 4 years (at the same time as the update to the labor-related share of the IPPS market basket); the first year of our current policy was FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482) for a detailed description of this methodology. For the FY 2014 IPPS/LTCH PPS final rule, we updated the COLA factors for Alaska and Hawaii published by OPM for 2009 using this methodology (78 FR 50997 through 50998). For the FY 2018 IPPS/LTCH PPS final rule, we again updated the COLA factors using this same methodology (82 FR 38539 through 38540). As discussed in this final rule, we continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii.

For FY 2022, we are updating the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Specifically, we are updating the 2009 OPM COLA factors by a comparison of the growth in the Consumer Price Indices (CPIs) for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We note that for the prior update to the COLA factors, we used the growth in the CPI for Anchorage and the CPI for Honolulu. Beginning in 2018, these indexes were renamed to the CPI for Urban Alaska and the CPI for Urban Hawaii, respectively, due to the BLS updating its sample to reflect the data from the 2010 decennial census on the distribution of the urban population (*https://www.bls.gov/regions/west/factsheet/2018cpirevisionwest.pdf,* accessed January 22, 2021). The CPI for Urban Alaska area covers Anchorage and Matanuska-Susitna Borough in the State of Alaska and the CPI for Urban Hawaii covers Honolulu in the State of Hawaii. BLS notes that the indexes are considered continuous over time, regardless of name or composition changes.

Because BLS publishes CPI data for only Urban Alaska and Urban Hawaii, using the methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we are using the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these urban areas and the United States (as measured by the CPIs mentioned previously) are appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the United States.

BLS publishes the CPI for All Items for Urban Alaska, Urban Hawaii, and for the average U.S. city. However, consistent with our methodology finalized in the FY 2013 IPPS/LTCH PPS final rule, we are creating reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share for the 2018-based IPPS market basket is comprised of a different mix of commodities and services. Therefore, we created reweighted indexes for Urban Alaska, Urban Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and using the approximate 57 percent commodities/43 percent services shares obtained from the 2018-based IPPS market basket. We created reweighted indexes using BLS data for 2009 through 2020—the most recent data available at the time of this final rulemaking. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38539 through 38540) we created reweighted indexes based on the 2014-based IPPS market basket (which was adopted for the FY 2018 IPPS update) and BLS data for 2009 through 2016 (the most recent BLS data at the time of the FY 2018 IPPS/LTCH PPS rulemaking).

We continue to believe this methodology is appropriate because we continue to make a COLA for LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the LTCH PPS standard Federal payment rate by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent. As stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38539 through 38540) under the COLA

update methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we exercised our discretionary authority to adjust payments to LTCHs in Alaska and Hawaii by incorporating this cap. In applying this finalized methodology for updating the COLA factors, we are continuing to use a cap of 25 percent, as our policy is based on OPM's COLA factors (updated by the methodology described previously). We received no comments on this proposal and therefore are finalizing this provision without modification.

Applying this methodology, the COLA factors that we are establishing effective for FY 2022 to adjust the nonlabor-related portion of the LTCH PPS standard Federal rate for LTCHs located in Alaska and Hawaii are shown in this table. For comparison purposes, we also are showing the COLA factors effective FY 2018 to FY 2021. We note that the COLA factors effective for FY 2022 for City and County of Honolulu, County of Kauai, and County of Maui and County of Kalawao are a result of applying the 25 percent cap as described previously.

Cost-of-Living Adjustment Factors (COLA): Alaska and Hawaii Under the LTCH PPS for FY2022

Area	FY 2018 through FY 2021	FY 2022 through FY 2025
Alaska:		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.25	1.22
Rest of Alaska	1.25	1.24
Hawaii:		
City and County of Honolulu	1.25	1.25
County of Hawaii	1.21	1.22
County of Kauai	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25

D. Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

In order to maintain budget neutrality, consistent with the budget neutrality requirement at § 412.523(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 4-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates

under the LTCH PPS and also are used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding CCRs and HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs, as previously noted, the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

Ordinarily, for this FY 2022 final rule, we would use IPPS total CCR data from the March 2021 update of the Provider Specific File (PSF) for the purposes of calculating the LTCH total CCR ceiling for FY 2022. However, for many IPPS hospitals, these IPPS total CCR data were derived from cost reports that ended during the COVID–19 PHE. As discussed in section VIII.A.4. of the preamble of this final rule, we believe the utilization patterns reflected in these cost reports were significantly impacted by the COVID–19 PHE. Since the IPPS total CCR data from the March 2020 update of the PSF was derived from cost reports ending prior to the COVID–19 PHE, we believe for the reasons discussed in section VIII.A.4. of the preamble of this final rule that these are the best available data at this time for the purposes of calculating the LTCH total CCR ceiling for FY 2022. Therefore, in this final rule, using our established methodology for determining the LTCH total CCR ceiling but using the IPPS total CCR data from the March 2020 update of the PSF, we are establishing an LTCH total CCR ceiling of 1.236 under the LTCH PPS for FY 2022 in accordance with § 412.525(a)(4)(iv)(C)(2) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48117 through 48119).)

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals as described above, without modification.

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Ordinarily, for this final rule, we would use IPPS total CCR data from the March 2021 update of the PSF for the purposes of determining the LTCH statewide average CCRs for FY 2022. However, for many IPPS hospitals, these IPPS total CCR data were derived from cost reports that ended during the COVID–19 PHE. As discussed in section VIII.A.4 of the preamble of this final rule, we believe the utilization patterns reflected in these cost reports were significantly impacted by the COVID–19 PHE. Since the IPPS total CCR data from the March 2020 update of the PSF was derived from cost reports ending prior to the COVID–19 PHE, for the reasons discussed in section VIII.A.4. of the preamble of this final rule, we believe that these are the best available data at this time for the purposes of determining the LTCH statewide average CCRs for FY 2022. Therefore, in this final rule, using our established methodology for determining the LTCH statewide average CCRs, but based on IPPS ''total CCR'' data from the March 2020 update of the PSF, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2021, through September 30, 2022, in Table 8C listed in section VI. of the Addendum to this final rule (and available via the internet on the CMS website).

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there were no short-term, acute care IPPS hospitals classified as rural or LTCHs located in these rural areas as of March 2020. Therefore, consistent with our existing methodology, we used the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C. While Massachusetts also has rural areas, the statewide average CCR for

rural areas in Massachusetts is based on one IPPS provider whose CCR is an atypical 0.949. Because this is much higher than the statewide urban average (0.459) and furthermore implies costs are nearly equal to charges, as with Connecticut, we used the national average total CCR for rural IPPS hospitals for rural Massachusetts in Table 8C. Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, as we proposed, we are continuing to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are using this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals as described above, without modification.

d. Reconciliation of HCO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2022

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments (that is, the target percentage) under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25735 through 25737), we proposed to adjust our methodology for calculating the applicable fixed-loss amount for FY 2022 for LTCH PPS standard Federal payment rate cases, while maintaining estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We specifically proposed to make a technical change to the methodology for determining the charge inflation factor that we apply to the charges on the MedPAR claims when calculating the fixed-loss amount for FY 2022. We also proposed to make a technical change to the methodology for determining the CCRs to use when calculating the fixed-loss amount for FY 2022. Furthermore, we proposed that these technical changes to the methodology for determining the charge inflation factor and the CCRs we use when calculating the fixed-loss amount would become a permanent part of our methodology for subsequent years as well. These technical changes that we proposed are described in greater detail in sections V.D.3.b.(1). and V.D.3.b.(2). of the Addendum to this final rule.

(1) Charge Inflation Factor for Use in Determining the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2022

Under the LTCH PPS, the cost of each claim is estimated by multiplying the charges on the claim by the provider's CCR. Due to the lag time in the availability of claims data, when estimating costs for the upcoming payment year we typically inflate the charges from the claims data by a uniform factor. Historically, as explained in in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59056), when determining the fixed-loss amount, charges were inflated with a growth factor calculated from quarterly market basket update values (determined by the Office of the Actuary). However, an analysis of the annual increase in actual charges (or charge inflation) calculated from the historical MedPAR claims compared with previous estimates using the quarterly market basket update values showed the actual charge inflation has been generally higher than the estimate. For example, when we set rates for FY 2019, we used a 2-year charge inflation factor of 5.7 percent based on the quarterly market basket update values. This factor was applied to charges from the FY 2017 MedPAR claims in order to inflate them to projected FY 2019 levels. However, our analysis of the actual FY 2019 MedPAR claims data shows that the actual growth in charges that occurred from FY 2017 to FY 2019 for standard Federal payment rate cases was 15.2 percent.

For greater accuracy in calculating the fixed-loss amount, we proposed to make a technical change to our methodology for determining the charge inflation factor. Similar to the method used under the IPPS hospital payment methodology (as discussed in section II.A.4.h.(2) of the Addendum to this final rule), we proposed to determine the LTCH charge inflation factor based on the historical growth in charges for LTCH PPS standard Federal payment rate cases, calculated using historical MedPAR

claims data, instead of using estimates calculated from quarterly market basket update values. In this section we describe the general methodology we proposed to use to calculate the charge inflation factor for FY 2022 and subsequent years. We discuss in greater detail later in this section our specific application of this proposal for FY 2022, including the specific data we proposed to use for FY 2022 after considering the impact the COVID–19 PHE had on the utilization patterns reflected in the FY 2020 LTCH data.

Step 1—Identify LTCH PPS Standard Federal Payment Rate Cases

The first step in our proposed methodology is to identify LTCH PPS standard Federal payment rate cases from the MedPAR claim files for the two most recently available Federal fiscal year time periods. For both fiscal years, consistent with our historical methodology for determining payment rates for the LTCH PPS, we remove any claims submitted by LTCHs that were all-inclusive rate providers as well as any Medicare Advantage claims. For both fiscal years, we also remove claims from providers that only had claims in one of the fiscal years.

Step 2—Remove Statistical Outliers

The next step in our proposed methodology is to remove all claims from providers whose growth in average charges was a statistical outlier. We remove these statistical outliers prior to calculating the charge inflation factor because we believe they may represent aberrations in the data that would distort the measure of average charge growth. To perform this statistical trim, we first calculate each provider's average charge in both fiscal years. Then, we calculate a charge growth factor for each provider by dividing its average charge in the most recent fiscal year by its average charge in the prior fiscal year. We then remove all claims for providers whose calculated charge growth factor was outside 3 standard deviations from the mean provider charge growth factor.

Step 3—Calculate the Charge Inflation Factor

The final step in our proposed methodology is to use the remaining claims to calculate a national charge inflation factor. We first calculate the average charge for those remaining claims in both fiscal years. We then calculate the national charge inflation factor by dividing the average charge in the more recent fiscal year by the average charge in the prior fiscal year.

As discussed in section VIII.A.4. of the preamble of the proposed rule, we proposed to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID–19 PHE. For the purposes of calculating the proposed charge inflation factor for FY 2022, we proposed to use the March 2020 update of the FY 2019 MedPAR file and the March 2019 update of the FY 2018 MedPAR as the basis of the LTCH PPS standard Federal payment rate cases for the two most recently available Federal fiscal year time periods, as described previously in our proposed methodology.

Therefore, for the proposed rule, we trimmed the March 2020 update of the FY 2019 MedPAR file and the March 2019 update of the FY 2018 MedPAR file using our proposed methodology. To compute the 1-year average annual rate-of-change in charges per case for FY 2022, we compared the average covered charge per case of $195,362 ($13,926,931,065/71,288 cases) from FY 2018 to the average covered charge per case of $207,224 ($14,172,496,534/68,392 cases) from FY 2019. This rate-of-change was 6.0723 percent and resulted in a proposed 1-year charge inflation factor of 1.060723, a proposed 2-year charge inflation factor of 1.125133 (calculated by squaring the proposed 1-year factor), and a proposed 3-year charge inflation factor of 1.193455 (calculated by cubing the proposed 1-year factor). We proposed to inflate the billed charges obtained from the FY 2019 MedPAR file by this 3-year charge inflation factor of 1.193455 when we determined the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2022.

(2) CCRs for Use in Determining the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2022

Historically, as explained in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59055 through 59056), when determining the fixed-loss amount, we used CCRs from the most recently available PSF file without any adjustment. By not making any adjustment, we assumed that CCRs in the current year would, on average, stay at the same level in the upcoming year. However, after examining actual changes to LTCH CCRs over time, we no longer believe this to be an appropriate assumption to make, as in general LTCH CCRs have not stayed at the same level year-to-year. For example, when we set rates for FY 2019, we assumed that CCRs would stay at the same level as the CCRs obtained from the March 2018 PSF. However, our calculations show that on average, CCRs declined 3.8 percent from March 2018 to March 2019.

For greater accuracy in calculating the fixed-loss amount, we proposed to adjust the methodology for determining the CCRs used to calculate the fixed-loss amount. Similar to the methodology used for IPPS hospitals (as discussed in section II.A.4.h.(2). of the Addendum to this final rule), we proposed to adjust CCRs obtained from the best available PSF data by an adjustment factor that is calculated based on historical changes in the average case weighted CCR for LTCHs. We believe these adjusted CCRs will more accurately reflect CCR levels in the upcoming payment year because they account for historical changes in the relationship between costs and charges for LTCHs. In this section, we describe the general methodology we proposed to use to calculate the CCR adjustment factor for FY 2022 and subsequent years. We discuss in greater detail later in this section our specific application of this proposal for FY 2022, including the specific data we proposed to use after considering the impact the COVID–19 PHE had on the utilization patterns reflected in the FY 2020 LTCH data.

Step 1—Assign Providers Their Historical CCRs

The first step in our proposed methodology is to identify providers with LTCH PPS standard Federal payment rate cases in the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims). For each of these providers, we then identify the CCR from the most recently available PSF. For each of these providers we also identify the CCR from the PSF that was made available 1 year prior to the most recently available PSF.

Step 2—Trim Providers With Insufficient CCR Data

The next step in our proposed methodology is to remove from the CCR adjustment factor calculation any providers for which we cannot accurately measure changes to their CCR using the PSF data. We first remove any provider whose CCR was missing in the most recent PSF or prior year PSF. We next remove any provider assigned the statewide average CCR for their State in either the most recent PSF or prior year PSF. We lastly remove any provider whose CCR was not updated between the most recent PSF and prior year PSF (determined by comparing the effective date of the records).

Step 3—Remove Statistical Outliers

The next step in our proposed methodology is to remove providers whose change in their CCR is a statistical outlier. To perform this statistical trim, for those providers remaining after application of Step 2, we calculate a provider-level CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year's PSF. We then remove any provider whose CCR growth factor was outside 3 standard deviations from the mean provider CCR growth factor. These statistical outliers are removed prior to calculating the CCR adjustment factor because we believe that they may represent aberrations in the data that would distort the measure of average annual CCR change.

Step 4—Calculate the CCR Adjustment Factor

The final step in our proposed methodology is to calculate, across all remaining providers after application of Step 3, the average case-weighted CCR from both the most recent PSF and prior year PSF. The provider case counts that we use to calculate the case-weighted average are determined from claims for LTCH standard Federal rate cases from the most recent MedPAR claims file. We note when determining these case counts, consistent with our historical methodology for determining the MS–LTC–DRG relative weights, we do not count short-stay-outlier claims as full cases but instead as a fraction of a case based on the ratio of covered days to the geometric mean length of stay for the MS–LTC–DRG grouped to the case. We calculate the national CCR adjustment factor by dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

In the proposed rule, we proposed to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID–19 PHE, for the reasons discussed in section VIII.A.4. of the preamble of the proposed rule. For the purposes of determining the CCRs used for calculating the proposed fixed-loss amount for FY 2022, we proposed to use the March 2020 PSF as the most recently available PSF and the March 2019 PSF as the PSF that was made available 1 year prior to the most recently available PSF, as described in our proposed methodology. In addition, we also proposed to use claims from the March 2020 update of the FY 2019 MedPAR file in our calculation of average case-weighted CCRs described in Step 4 of our proposed methodology.

Specifically, to calculate the CCRs we proposed to use in the proposed rule, we followed the proposed methodology described previously and, for providers with LTCH PPS standard Federal payment rate cases in the March 2020 update of the FY 2019 MedPAR file, we identified their CCRs from both the March 2019 PSF and March 2020 PSF. After performing the trims outlined in our proposed methodology, we used the LTCH PPS standard Federal payment rate case counts from the FY 2019 MedPAR file (classified using proposed Version 39 of the GROUPER) to calculate the case-weighted average CCRs. For the proposed rule, we calculated a proposed March 2019 national average case-weighted CCR of 0.256374 and a proposed March 2020 national average case-weighted CCR of 0.246517. We then calculated the proposed national CCR adjustment factor by dividing the March 2020 national average case-weighted CCR by the March 2019 national average case-weighted CCR. This resulted in a proposed 1-year national CCR adjustment factor of 0.961555 and a proposed 2-year national CCR adjustment factor of 0.924588 (calculated by squaring the proposed 1-year factor). When calculating the proposed fixed-loss amount for FY 2022, we assigned the statewide average CCR for the upcoming fiscal year to all providers who were assigned the statewide average in the March 2020 PSF or whose CCR was missing in the March 2020 PSF. For all other providers, we multiplied their CCR from the March 2020 PSF by the proposed 2-year national CCR adjustment factor.

(3) Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2022

In the proposed rule, we proposed no other changes to our methodology for calculating the proposed applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases. Therefore, for FY 2022, using the best available data, we calculated a proposed fixed-loss amount that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in the proposed rule). As described earlier in this section and discussed in more detail in section VIII.A.4. of the preamble of the proposed rule, we believe the FY 2020 MedPAR claims were significantly impacted by COVID–19 PHE. As a result, we proposed to use LTCH claims data from the March 2020 update of the FY 2019 MedPAR file to calculate a proposed fixed-loss amount for FY 2022. Therefore, based on LTCH claims data from the March 2020 update of the FY 2019 MedPAR file adjusted for charge inflation and adjusted CCRs from the March 2020 update of the PSF, we proposed a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2022 of $32,680 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2022 payments for such cases.

Comment: We received multiple comments on the technical changes we proposed to make to the methodology for calculating the applicable fixed-loss amount for FY 2022 for LTCH PPS standard Federal payment rate cases. A commenter was supportive of the technical changes we proposed.

Another commenter objected to the technical changes we proposed stating that these changes resulted in a significant increase to the proposed FY 2022 fixed-loss amount for LTCH PPS standard Federal payment rate cases. The commenter stated that this increase will lead to a reduction in high-cost outlier payments and can be avoided if CMS does not adopt the proposed methodology changes. The commenter stated that it was unclear why CMS would propose these technical changes that more closely align with the IPPS fixed-loss threshold methodology when CMS has historically always used a different methodology for the LTCH PPS. The commenter also explained that they attempted to replicate CMS' methodology and calculate the proposed fixed loss amount, but were unable to approximate the proposed fixed-loss amount. The commenter believes that CMS may have made an additional change to the methodology that was not disclosed in the proposed rule. Specifically, the commenter believes that CMS may be applying a wage index adjustment when determining LTCH PPS fixed-loss threshold, similar to the adjustment that CMS applies when determining the IPPS fixed-loss threshold.

Another commenter opposed the proposed increase in the fixed-loss amount from FY 2021. The commenter stated that the increase will result in a significant reduction in the number of cases that qualify as high-cost outliers and that to the extent that increases in the fixed-loss amount are necessary, they should be limited to no more than the market basket percent increase in any given year.

Response: In response to the comments that expressed concern over the magnitude of the proposed increase in the fixed-loss amount, we remind the reader that in accordance with § 412.525(a)(2)(ii), which implements section 1886(m)(7)(b) of the Act, our proposed methodology projected that the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases would result in total outlier payments for FY 2022 being equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. An analysis we conducted on the historical MedPAR claims showed that high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments exceeded the 7.975 percent target in every fiscal year since FY 2016. We currently project that in FY 2021 high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will be approximately 8.8 percent. We believe our proposed changes improve the accuracy of our model, for the reasons explained in the proposed rule, and will result in fixed-loss amounts that lead to actual outlier payments being closer to the statutory 7.975 percent target than would occur if we did not incorporate our proposed changes.

In response to the commenter that believes we may have made an additional change to our methodology that was not disclosed in the proposed rule, we confirm that no other changes to methodology were made when determining the proposed fixed-loss amount for FY 2022. We are unable to determine with the information provided any reason the commenter was unable to approximate the proposed fixed-loss amount.

After considering the comments received, we are finalizing, without modification, the changes we proposed to our methodology for calculating the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases. Therefore, in this final rule, we followed the methodology explained in section V.D.3.b.(1). of the Addendum to this final rule to determine the charge inflation factor that we apply to the charges on the MedPAR claims when calculating the fixed-loss amount for FY 2022. As discussed in section VIII.A.4. of the preamble of this final rule, we are proposing to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID–19 PHE. For the purposes of calculating the charge inflation factor for FY 2022, we used the March 2020 update of the FY 2019 MedPAR file and the March 2019 update of the FY 2018 MedPAR as the basis of the LTCH PPS standard Federal payment rate cases for the two most recently available Federal fiscal year time periods, as described previously in our methodology. As discussed in greater detail in section VIII.A.4. of the preamble of this final rule, due to the significant impact that the COVID–19 PHE had on the utilization patterns reflected in the FY 2020 MedPAR claims, we believe these are the best available data at this time for the purposes of calculating the charge inflation factor for FY 2022.

Therefore, for this final rule, we trimmed the March 2020 update of the FY 2019 MedPAR file and the March 2019 update of the FY 2018 MedPAR file using our finalized methodology. To compute the 1-year average annual rate-of-change in charges per case for FY 2022, we compared the average covered charge per case of $195,362 ($13,926,931,065/71,288 cases) from FY 2018 to the average covered charge per case of $207,224 ($14,172,496,534/68,392 cases) from FY 2019. This rate-of-change was 6.0723 percent and results in a 1-year charge inflation factor of 1.060723, a 2-year charge inflation factor of 1.125133 (calculated by squaring the 1-year factor), and a 3-year charge inflation factor of 1.193455 (calculated by cubing the 1-year factor). We inflated the billed charges obtained from the FY 2019 MedPAR file by this 3-year charge inflation factor of 1.193455 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2022.

In this final rule, we followed the methodology explained in section V.D.3.b.(2). of the Addendum to this final rule to determine the CCRs to use when calculating the fixed-loss amount for FY 2022. In this final rule, we are using the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID–19 PHE, for the reasons discussed in section VIII.A.4. of the preamble of this final rule. Ordinarily, for this FY 2022 final rule, we would use CCR data from the March 2021 update of the PSF when determining the CCRs used for calculating the fixed-loss amount for FY 2022. However, for many LTCHs, these CCR data were derived from cost reports that ended during the COVID–19 PHE. Therefore, as we proposed, for the purposes of determining the CCRs used for calculating the fixed-loss amount for FY 2022, we are using the March 2020 PSF as the most recently available PSF and the March 2019 PSF as the PSF that was made available 1 year prior to the most recently available PSF, as described in our methodology. Since the CCR data from the March 2020 update of the PSF was derived from cost reports ending prior to the COVID–19 PHE, as discussed in section VIII.A.4. of the preamble of this final rule, we believe these are the best available data at this time for the purposes of determining the CCRs used to calculate the fixed-loss amount for FY 2022. In addition, as we proposed, we also are using claims from the March 2020 update of the FY 2019 MedPAR file in our calculation of average case-weighted CCRs described in Step 4 of our methodology. As discussed in greater detail in section VIII.A.4. of the preamble of this final rule, due to the significant impact that the COVID–19 PHE had on the utilization patterns reflected in the FY 2020 MedPAR claims, we believe these are the best available data at this time for the purposes of calculating the average case-weighted CCRs.

Specifically, to calculate the CCRs to use in this final rule, we followed our finalized methodology described previously and, for providers with LTCH PPS standard Federal payment rate cases in the March 2020 update of the FY 2019 MedPAR file, we identified their CCRs from both the March 2019 PSF and March 2020 PSF. After performing the trims outlined in our methodology, we used the LTCH PPS standard Federal payment rate case counts from the FY 2019 MedPAR file (classified using finalized Version 39 of the GROUPER) to calculate the case-weighted average CCRs. For this final rule, we calculated a March 2019 national average case-weighted CCR of 0.256374 and a March 2020 national average case-weighted CCR of 0.246517. We then calculated the national CCR adjustment factor by dividing the March 2020 national average case-weighted CCR by the March 2019 national average case-weighted CCR. This results in a 1-year national CCR adjustment factor of 0.961554 and a 2-year national CCR adjustment factor of 0.924586 (calculated by squaring the 1-year factor). When calculating the fixed-loss amount for FY 2022, we assigned the statewide average CCR for the upcoming fiscal year to all providers who were assigned the statewide average in the March 2020 PSF or whose CCR was missing in the March 2020 PSF. For all other providers, we multiplied their CCR from the March 2020 PSF by the 2-year national CCR adjustment factor.

For FY 2022, using the best available data, we calculated a fixed-loss amount that would maintain estimated HCO payments at the projected 7.975 percent

of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in the final rule). As described earlier in this section and discussed in more detail in section VIII.A.4. of the preamble of this final rule, we believe the FY 2020 MedPAR claims were significantly impacted by COVID–19 PHE. As a result, we are using LTCH claims data from the March 2020 update of the FY 2019 MedPAR file to calculate a fixed-loss amount for FY 2022. Therefore, based on LTCH claims data from the March 2020 update of the FY 2019 MedPAR file adjusted for charge inflation and adjusted CCRs from the March 2020 update of the PSF, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are finalizing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2022 of $33,015 that will result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2022 payments for such cases.

We also are continuing to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $33,015).

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FYs 2019 through 2021, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases, FY 2018 and FY 2019 claims for these cases were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2021, at that time our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2021 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2021. In particular, in FY 2021, we established the fixed-loss amount for site neutral payment rate cases as the FY 2021 IPPS fixed-loss amount of $29,064 (as corrected at 85 FR 78756).

As noted earlier, because not all claims in the data used for this FY 2022 IPPS/LTCH PPS final rule were subject to the unblended site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2021 when developing a fixed-loss amount for site neutral payment rate cases for FY 2022. Our actuaries continue to project that site neutral payment rate cases in FY 2022 will continue to mirror an IPPS case paid under the same MS–DRG. That is, our actuaries continue to project that the costs and resource use for FY 2022 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. (Based on the FY 2019 LTCH claims data used in the development of this FY 2022 IPPS/LTCH PPS final rule, approximately 75 percent of LTCH cases were paid the LTCH PPS standard Federal payment rate and approximately 25 percent of LTCH cases were paid the site neutral payment rate for discharges occurring in FY 2019.)

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2022 is the IPPS fixed-loss amount for FY 2022. Therefore, consistent with past practice, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25738), we proposed that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we proposed a fixed-loss amount for site neutral payment rate cases of $30,967, which is the same FY 2022 IPPS fixed-loss amount discussed in section II.A.4.j.(1). of the Addendum to the proposed rule. Accordingly, for FY 2022, we proposed to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $30,967).

Comment: Some commenters opposed the proposed fixed-loss amount for site neutral payment rate cases. A commenter stated that increases in the fixed-loss threshold for site neutral payment rate cases should be limited to no more than the market basket percent increase. Another commenter stated that

site neutral patients have greater resource use and costs, on average, than IPPS hospital patients assigned to the same DRGs. Therefore the ''significant increase'' in the proposed fixed-loss amount for site neutral payment rate cases will be magnified for LTCHs treating high-cost Medicare patients. The commenter also stated that compared to IPPS hospitals, LTCHs have a greater concentration of discharges in only a few MS–LTC–DRGs and therefore even small changes to the IPPS fixed-loss threshold can have significant impact on LTCH PPS payments for site-neutral cases.

Response: As already stated, our actuaries continue to project that site neutral payment rate cases in FY 2022 will continue to mirror an IPPS case paid under the same MS–DRG. That is, our actuaries continue to project that the costs and resource use for FY 2022 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS DRG, on average, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2022 is the IPPS fixed-loss amount for FY 2022.

Therefore, after considering public comments on our proposals, we are finalizing our proposals as described above, without modification. Therefore, for FY 2022, as we proposed, we are establishing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed loss amount. That is, we are establishing a fixed-loss amount for site neutral payment rate cases of $30,988, which is the same FY 2022 IPPS fixed-loss amount discussed in section II.A.4.j.(1). of the Addendum to this final rule. Accordingly, under this policy, for FY 2022, we will calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the fixed-loss amount for site neutral payment rate cases of $30,988).

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2022 would not result in any increase in estimated aggregate FY 2022 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2022, in general, we proposed to continue this policy.

As explained in the proposed rule, consistent with the IPPS HCO payment threshold, we estimate the proposed fixed-loss threshold would result in FY 2022 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2022 would not result in any increase in estimated aggregate FY 2022 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), as we explained in the proposed rule, it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2022. In order to achieve this, for FY 2022, we proposed to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as $1.0 - 5.1/100 = 0.949$) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

Comment: Some commenters, as they have done since the inception of the dual rate payment system that created the site neutral payment rate, objected to the proposed site neutral payment rate HCO budget neutrality adjustment. The commenters' primary objection continued to be based on their belief that, because the IPPS base rates used in the IPPS comparable per diem amount calculation of the site neutral payment rate include a budget neutrality adjustment for IPPS HCO payments (for example, a 5.1 percent adjustment on the operating IPPS standardized amount), a ''second'' budget neutrality factor is not necessary and is, in fact, redundant and results in a systematic reduction of LTCH site-neutral payments.

Response: We continue to disagree with the commenters that a budget neutrality adjustment for site neutral payment rate HCO payments is unnecessary or duplicative. We have stated such disagreement during each previous rulemaking cycle. We refer readers to 84 FR 42648 through 42649, 83 FR 41737 through 41738, 82 FR 38545 through 38546, 81 FR 57308 through 57309, and 80 FR 49621 through 49622 for more information on our responses to these comments.

After consideration of public comments, for the reasons discussed above, we are adopting our proposed site neutral payment rate HCO budget neutrality adjustment as final without modification. Specifically, for FY 2022, as we proposed, we are applying a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as $1.0 - 5.1/100 = 0.949$) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this HCO budget neutrality adjustment will not apply to the HCO portion of the site neutral payment rate amount.

E. Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they

otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25739), based on the data available at that time, we proposed to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 79.11 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we proposed that, if more recent data became available, we would use that data to determine this factor in the final rule.

We did not receive any public comments in response to our proposal, and we are adopting it as final. However, as we proposed, we are determining the factor in this final rule using more recent data. For FY 2022, as discussed in greater detail in section V.E.4.b. of the preamble of this final rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 68.57 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2022. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 51.43 percent (the product of 75 percent and 68.57 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2022, we project that the reduction in the amount of Medicare DSH payments under section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 76.43 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 51.43 percent = 76.43 percent).

Therefore, for FY 2022, consistent with our proposal, we are establishing that the calculation of the ''IPPS comparable amount'' under § 412.529 will include an applicable operating Medicare DSH payment amount that is equal to 76.43 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act.

F. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2022

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the FY 2022 values are shown in Tables 12A through 12B listed in section VI. of the Addendum to this final rule and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the final FY 2022 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this final rule, we are establishing an LTCH PPS standard Federal payment rate for FY 2022 of $44,713.67, as discussed in section V.A. of the Addendum to this final rule. We illustrate the methodology to adjust the LTCH PPS standard Federal payment rate for FY 2022 in the following example:

Example:

During FY 2022, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a FY 2022 LTCH PPS wage index value of 1.0372 (obtained from Table 12A listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2022 of 0.9448 (obtained from Table 11 listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website). The LTCH submitted quality reporting data for FY 2022 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2022, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2022 LTCH PPS standard Federal payment

rate ($44,713.67) by the labor-related share (0.679 percent) and the wage index value (1.0372). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (0.321 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which is then multiplied by the MS–LTC–DRG relative weight (0.9448) to calculate the total adjusted LTCH PPS standard Federal prospective payment for FY 2022 ($43,312.54). The table illustrates the components of the calculations in this example.

Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$44,713.67
Labor-Related Share	x 0.679
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $30,360.58
Wage Index (CBSA 16984)	x 1.0372
Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $31,489.99
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($44,713.67 x 0.321)	+ $14,353.09
Adjusted LTCH PPS Standard Federal Payment Amount	= $45,843.08
MS-LTC-DRG 189 Relative Weight	x 0.9448
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $43,312.54

VI. Tables Referenced in This Final Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this final rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2021, for the FY 2022 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available through the internet. Specifically, all IPPS tables listed in the final rule, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available through the internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules. For additional discussion of the information included in the IPPS and LTCH PPS tables associated with the IPPS/LTCH PPS proposed and final rules, as well as prior changes to the information included in these tables, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59059 through 59060).

In addition, under the HAC Reduction Program, established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. The hospital-level data for the FY 2022 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

As was the case for the FY 2021 IPPS/LTCH PPS proposed and final rules, we are no longer including Table 15, which had typically included the fiscal year readmissions payment adjustment factors because hospitals have not yet had the opportunity to review and correct the data before the data are made public under our policy regarding the reporting of hospital-specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2022, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2022 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2021. We expect Table 15 will be posted on the CMS website in the fall of 2021.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified in this final rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this final rule are generally available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2022 IPPS Final rule Home Page'' or ''Acute Inpatient -Files- for Download.''

Table 2—Case-Mix Index and Wage Index Table by CCN—FY 2022 Final Rule
Table 3—Wage Index Table by CBSA—FY 2022 Final Rule
Table 4A—List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2022 Final Rule
Table 4B—Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2022 Final Rule
Table 5— List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2022
Table 6A—New Diagnosis Codes—FY 2022
Table 6B—New Procedure Codes—FY 2022
Table 6C—Invalid Diagnosis Codes—FY 2022
Table 6D—Invalid Procedure Codes—FY 2022
Table 6E—Revised Diagnosis Code Titles—FY 2022
Table 6F—Revised Procedure Code Titles—FY 2022
Table 6G.1—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2022
Table 6G.2—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2022
Table 6H.1—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2022
Table 6H.2—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2022
Table 6I—Complete MCC List—FY 2022
Table 6I.1—Additions to the MCC List—FY 2022
Table 6I.2—Deletions to the MCC List—FY 2022
Table 6J—Complete CC List—FY 2022
Table 6J.1—Additions to the CC List—FY 2022
Table 6J.2—Deletions to the CC List—FY 2022
Table 6K— Complete List of CC Exclusions—FY 2022
Table 6P— ICD–10–CM and ICD–10–PCS Codes for MS–DRG Changes—FY 2022 (Table 6P contains multiple tables, 6P.1a. through 6P.3a that

include the ICD–10–CM and ICD–10–PCS code lists relating to specific MS–DRG changes. These tables are referred to throughout section II.D. of the preamble of this final rule.)

Table 7A—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update March 2020—GROUPER Version 38 MS–DRGs

Table 7B—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update March 2020—GROUPER Version 39 MS–DRGs

Table 8A—Final FY 2022 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B—Final FY 2022 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 18—Final FY 2022 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2022 final rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1752–F:

Table 8C—FY 2022 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2021 through September 30, 2022

Table 12A—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2021 through September 30, 2022

Table 12B—LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2021 through September 30, 2022

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TABLE 1A.—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2022

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.0 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = -0.025 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.325 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.7 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,138.28	$1,983.43	$4,056.12	$1,944.05	$4,110.89	$1,970.30	$4,028.74	$1,930.93

TABLE 1B.—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2022

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.0 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = -0.025 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.325 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.7 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,795.46	$2,326.25	$3,720.11	$2,280.06	$3,770.34	$2,310.85	$3,695.00	$2,264.67

TABLE 1C.—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2022

	Rates if Wage Index Greater Than 1		Hospital is a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 2.0)		Hospital is NOT a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 1.325)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$3,795.46	$2,326.25	$3,770.34	$2,310.85

[1] For FY 2022, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.—CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2022

	Rate
National	$472.60

TABLE 1E.— LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2022

	Full Update (1.9 Percent)	Reduced Update* (-0.1 Percent)
Standard Federal Rate	$44,713.67	$43,836.08

* For LTCHs that fail to submit quality reporting data for FY 2022 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

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Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary in order to make payment and policy changes under the IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also, as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

In this final rule, we are repealing the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021. We are also repealing the market-based MS–DRG relative weight methodology that was adopted effective for FY 2024, and to continue using the existing cost-based MS–DRG relative weight methodology to set Medicare payment rates for inpatient stays for FY 2024 and subsequent fiscal years. As discussed in section V.L. of the preamble of this final rule, we believe we need to further consider the questions raised regarding the ability for this data to represent market-based pricing given the relationship between Medicare FFS and MA organization rates, and therefore the usefulness and appropriateness of this data for Medicare FFS ratesetting purposes. In addition, this final rule finalizes the Medicare wage index provisions adopted in our May 10, 2021 interim final rule with comment period (CMS–1762–IFC), which amended current regulations to allow hospitals with a rural redesignation to reclassify through the Medicare Geographic Classification Review Board using the rural reclassified area as the geographic area in which the hospital is located. These regulatory changes align our policy with the decision in *Bates County Memorial Hospital* v. *Azar,* 464 F. Supp. 3d (D.D.C. 2020).

Section 1886(b)(3)(B)(viii) of the Act requires subsection (d) hospitals to report data in accordance with the requirements of the Hospital IQR Program for purposes of measuring and making publicly available information on health care quality, and links the quality data submission to the annual applicable percentage increase. Sections 1886(b)(3)(B)(ix), 1886(n), and 1814(l) of the Act require eligible hospitals and CAHs to

demonstrate they are meaningful users of certified EHR technology for purposes of electronic exchange of health information to improve the quality of health care, and links the submission of information demonstrating meaningful use to the annual applicable percentage increase for eligible hospitals and the applicable percent for CAHs. Section 1886(m)(5) of the Act requires each LTCH to submit quality measure data in accordance with the requirements of the LTCH QRP for purposes of measuring and making publicly available information on health care quality, and in order to avoid a 2-percentage point reduction. Section 1886(o) of the Act requires value-based incentive payments for subsection (d) hospitals that meet the performance standards established under the Hospital VBP Program on an announced set of quality and efficiency measures for the purpose of measuring, linking measure performance to payment, and making publicly available information on health care quality. Section 1886(p) of the Act requires a reduction in payment for subsection (d) hospitals that rank in the worst-performing 25 percent with respect to measures of hospital-acquired conditions under the HAC Reduction Program for the purpose of measuring, linking measure performance to payment, and making publicly available information on health care quality. Section 1886(q) of the Act requires a reduction in payment for subsection (d) hospitals for excess readmissions based on measures for applicable conditions under the hospital Readmissions Reduction Program for the purpose of measuring, linking measure performance to payment, and making publicly available information on health care quality. Section 1866(k) of the Act applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') and requires PCHs to report data in accordance with the requirements of the PCHQR Program for purposes of measuring and making publicly available information on health care quality, however, there is no link to PCHs' payments. In this final rule, we are adopting new measures, including a Maternal Morbidity Structural Measure for the Hospital IQR Program and the COVID–19 Vaccination Coverage Among Health Care Personnel measure for the Hospital IQR Program, PCHQR Program, and the LTCH QRP, removing certain existing measures, and updating other administrative requirements. For the reasons described throughout this final rule for each change, we believe that the changes in this final rule, including the updates to the IPPS and LTCH PPS rates, the repeal of the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge by MS–DRG, the repeal the market-based MS–DRG relative weight methodology, and the policies and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action(s) and/or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act)''. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. We estimate that the changes for FY 2022 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $2.3 billion increase in FY 2022 payments, primarily driven by: (a) A combined $1.6 billion increase in FY 2022 operating payments, including uncompensated care payments and the recently enacted statutory provision that provides for an imputed floor adjustment for all-urban States in a non-budget neutral manner beginning in FY 2022 and discussed in section III.G.2. of this rule, and (b) a combined increase of $0.7 billion resulting from estimated changes in new technology add-on payments, and FY 2022 capital payments. These changes are relative to payments made in FY 2021. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by approximately $42 million in FY 2022 relative to FY 2021.

Our operating impact estimate includes the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this final rule. In addition, our operating payment impact estimate includes the 2.0 percent hospital update to the standardized amount (which includes the estimated 2.7 percent market basket update reduced by 0.7 percentage point for the productivity adjustment). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this final rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this final rule contains a range of policies, we refer readers to the section of the final rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy

changes, as well as statutory changes effective for FY 2022, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in variables such as admissions, lengths of stay, case mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific policies in the discussion of those policies as needed.

E. Hospitals Included In and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital related- costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 27 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As discussed in section II.A.4 of the Addendum to this final rule, consistent with our use of the Provider Specific File (PSF), we included 3,195 IPPS acute care hospitals in our analysis. This represents approximately 53 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,420 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, cancer hospitals, extended neoplastic disease care hospital, and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the update and policy changes to the LTCH PPS for FY 2022 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As discussed in section II.A.4. of the Addendum to this final rule, consistent with our use of the PSF, there were 94 children's hospitals, 11 cancer hospitals, 6 short term-acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, 1 extended neoplastic disease care hospital, and 15 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, the rehabilitation hospitals and units, and the LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and the psychiatric hospitals and units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this final rule. The impacts of the changes on LTCHs are discussed in section I.J. of this Appendix.

For the children's hospitals, cancer hospitals, short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2022 percentage increase in the 2018-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's 2021 second quarter forecast of the 2018-based IPPS market basket increase, we are estimating the FY 2022 update to be 2.7 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section IV.A. of the preamble of this final rule. We used the more recent data available for this final rule to calculate the IPPS operating market basket update for FY 2022. However, the Affordable Care Act requires a productivity adjustment (0.7 percentage point reduction for FY 2022), resulting in a 2.0 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.A. of the preamble of this final rule. Children's hospitals, cancer hospitals, short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the 2018-based IPPS operating market basket for FY 2022, estimated at 2.7 percent.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 Percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing policy changes and payment rate updates for the IPPS for FY 2022 for operating costs of acute care hospitals. The FY 2022 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2022 operating payments will increase by 2.6 percent, compared to FY 2021. In addition to the applicable percentage increase, this amount reflects the 0.5 percentage point permanent adjustment to the standardized amount required under section 414 of MACRA. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the changes to each system. This section deals with the changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the best available claims data to enable us to estimate the impacts on payments per case of certain changes in this final rule. As discussed in section I.A of this final rule, we believe that the FY 2019 claims data is the best available data for purposes of the FY 2022 ratesetting and this impact analysis reflects the use of that data. However, there are other changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented in this section are taken from the FY 2019 MedPAR file and are consistent with our use of Provider-Specific File (PSF) data, as discussed previously in this final rule. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the best available hospital cost reports were used to categorize hospitals, specifically, cost report data from the FY 2018 HCRIS, as also discussed previously in this final rule. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each

change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2019 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, and the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2022 are discussed in section I.I. of this Appendix.

We discussed the following changes:

- The effects of the application of the applicable percentage increase of 2.0 percent (that is, a 2.7 percent market basket update with a reduction of 0.7 percentage point for the productivity adjustment), and a 0.5 percentage point adjustment required under section 414 of the MACRA to the IPPS standardized amount, and the applicable percentage increase (including the market basket update and the productivity adjustment) to the hospital-specific rates.
- The effects of the changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2018, compared to the FY 2017 wage data, to calculate the FY 2022 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this final rule) that will be effective for FY 2022.
- The effects of the rural floor with the application of the national budget neutrality factor to the wage index.
- The effects of the imputed floor wage index adjustment. This provision is not budget neutral.
- The effects of the frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2022. This provision is not budget neutral.
- The total estimated change in payments based on the FY 2022 policies relative to payments based on FY 2021 policies.

To illustrate the impact of the FY 2022 changes, our analysis begins with a FY 2021 baseline simulation model using: The FY 2021 applicable percentage increase of 2.4 percent; the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount; the FY 2021 MS–DRG GROUPER (Version 38); the FY 2021 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2021 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner, and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act will receive an applicable percentage increase of 1.325 percent. At the time this impact was prepared, 68 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2022 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the payment changes for FY 2022 using a reduced update for these hospitals.

For FY 2022, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of -0.025 percent. At the time this impact analysis was prepared, 97 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2022 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the payment changes for FY 2022 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of -0.7 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time this impact was prepared, 24 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2022 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2022 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the percent change in payments per case from FY 2021 to FY 2022. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2022 using a applicable percentage increase of 2.0 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.7 percent with a 0.7 percentage point reduction for the productivity adjustment. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users will receive an update of 1.325 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive a update of -0.025 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive an update of -0.7 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs is also equal to the applicable percentage increase, or 2.0 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the changes in hospitals' payments per case from FY 2021 to FY 2022 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2021 that are no longer reclassified in FY 2022. Conversely, payments may increase for hospitals not reclassified in FY 2021 that are reclassified in FY 2022.

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2022. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,195 acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: Urban and rural. There are 2,459 hospitals located in urban areas and 736 hospitals in rural areas included in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2022 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 1,983, and 1,212, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,031 nonteaching hospitals in our analysis, 907 teaching hospitals with fewer than 100 residents, and 257 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs, MDHs and RRCs). There were 523 RRCs, 305 SCHs, 153 MDHs, 154 hospitals that are both SCHs and RRCs, and 27 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total inpatient days. These data were taken from the FY 2018 or FY 2017 Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2022 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act.

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TABLE I.—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2022

	Number of Hospitals [1]	Hospital Rate Update and Adjustment under MACRA (1) [2]	FY 2022 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3]	FY 2022 Wage Data with Application of Wage Budget Neutrality (3) [4]	FY 2022 MGCRB Reclassifications (4) [5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Imputed Floor Wage Index (6) [7]	Application of the Frontier State Wage Index and Outmigration Adjustment (7) [8]	All FY 2022 Changes (8) [9]
All Hospitals	3,195	2.5	0.0	0.0	0.0	0.0	0.2	0.1	2.6
By Geographic Location:									
Urban hospitals	2,459	2.5	0.0	0.0	-0.1	0.0	0.2	0.1	2.6
Rural hospitals	736	2.2	0.1	0.2	1.3	-0.2	0.0	0.1	2.8
Bed Size (Urban):									
0-99 beds	634	2.4	0.0	0.1	-0.6	0.1	0.2	0.3	2.7
100-199 beds	754	2.5	0.0	0.0	-0.2	0.2	0.2	0.2	2.6
200-299 beds	427	2.5	0.0	0.1	0.2	0.0	0.2	0.1	2.4
300-499 beds	421	2.5	0.0	0.0	0.1	0.0	0.1	0.1	2.6
500 or more beds	223	2.5	0.0	-0.1	-0.3	0.0	0.2	0.0	2.6
Bed Size (Rural):									
0-49 beds	311	2.1	0.1	0.3	0.7	-0.1	0.0	0.2	4.3
50-99 beds	253	2.1	0.1	0.2	0.8	-0.1	0.0	0.2	2.4
100-149 beds	94	2.2	0.1	0.2	1.3	-0.2	0.0	0.0	2.5
150-199 beds	39	2.3	0.0	0.2	1.6	-0.2	0.0	0.1	2.6
200 or more beds	39	2.3	0.0	0.3	2.0	-0.3	0.0	0.0	2.8
Urban by Region:									
New England	112	2.5	0.0	-1.0	0.8	3.7	0.6	0.1	2.7
Middle Atlantic	304	2.5	0.0	-0.2	0.3	-0.4	0.5	0.2	2.5
East North Central	381	2.5	0.0	-0.2	-0.2	-0.4	0.0	0.0	2.4
West North Central	160	2.4	-0.1	0.2	-0.6	-0.3	0.0	0.6	2.7
South Atlantic	402	2.5	0.0	0.3	-0.5	-0.3	0.2	0.0	2.9
East South Central	144	2.5	0.0	0.1	-0.3	-0.3	0.0	0.0	2.5
West South Central	364	2.5	0.0	-0.3	-0.5	-0.3	0.0	0.0	2.3
Mountain	172	2.4	0.0	0.2	0.1	-0.1	0.0	0.2	2.6
Pacific	370	2.4	-0.1	0.5	0.2	0.4	0.0	0.1	2.5
Puerto Rico	50	2.5	-0.5	-0.3	-1.0	0.2	0.0	0.1	1.7
Rural by Region:									
New England	19	2.3	0.0	-0.4	1.3	-0.3	0.2	0.0	3.4
Middle Atlantic	50	2.2	0.1	0.3	1.0	-0.2	0.0	0.0	2.6
East North Central	113	2.2	0.1	0.2	0.9	-0.1	0.0	0.0	2.2
West North Central	89	2.1	0.0	0.1	0.3	-0.1	0.0	0.2	2.8
South Atlantic	114	2.2	0.1	1.1	1.6	-0.2	0.0	0.0	3.0
East South Central	144	2.4	0.1	-0.1	1.8	-0.3	0.0	0.1	2.6
West South Central	135	2.2	0.1	0.0	2.8	-0.3	0.0	0.0	3.0
Mountain	48	1.9	0.0	0.6	-0.1	-0.1	0.0	0.8	1.9
Pacific	24	2.1	0.0	-0.1	1.1	-0.1	0.0	0.0	5.2
By Payment Classification:									
Urban hospitals	1,983	2.5	0.0	0.0	-0.6	0.2	0.2	0.1	2.6

	Number of Hospitals [1]	Hospital Rate Update and Adjustment under MACRA (1) [2]	FY 2022 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3]	FY 2022 Wage Data with Application of Wage Budget Neutrality (3) [4]	FY 2022 MGCRB Reclassifications (4) [5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Imputed Floor Wage Index (6) [7]	Application of the Frontier State Wage Index and Outmigration Adjustment (7) [8]	All FY 2022 Changes (8) [9]
Rural areas	1,212	2.4	0.0	0.0	0.9	-0.3	0.1	0.1	2.6
Teaching Status:									
Nonteaching	2,031	2.4	0.0	0.2	0.1	0.1	0.1	0.1	2.7
Fewer than 100 residents	907	2.5	0.0	0.0	0.1	-0.1	0.2	0.2	2.5
100 or more residents	257	2.4	0.0	-0.1	-0.2	0.0	0.2	0.0	2.6
Urban DSH:									
Non-DSH	502	2.5	0.0	0.0	-0.6	0.0	0.3	0.2	2.6
100 or more beds	1,227	2.5	0.0	0.0	-0.6	0.2	0.2	0.1	2.6
Less than 100 beds	348	2.5	0.0	0.1	-0.5	0.2	0.1	0.2	2.7
Rural DSH:									
SCH	265	2.0	0.0	0.1	0.2	0.0	0.0	0.1	2.5
RRC	608	2.4	0.0	0.0	1.0	-0.3	0.1	0.1	2.6
100 or more beds	30	2.5	0.1	-0.1	0.1	-0.4	0.0	0.0	1.5
Less than 100 beds	215	2.3	0.1	0.3	1.0	-0.3	0.0	0.2	3.2
Urban teaching and DSH:									
Both teaching and DSH	679	2.5	0.0	-0.1	-0.6	0.1	0.3	0.1	2.6
Teaching and no DSH	74	2.5	0.0	-0.1	-0.9	0.6	0.4	0.2	2.4
No teaching and DSH	896	2.5	0.0	0.2	-0.5	0.4	0.1	0.1	2.6
No teaching and no DSH	334	2.5	0.0	0.1	-0.6	-0.2	0.3	0.3	2.6
Special Hospital Types:									
RRC	523	2.5	0.0	0.0	1.0	-0.4	0.1	0.1	2.6
SCH	305	2.0	0.0	0.1	0.1	0.0	0.0	0.0	2.5
MDH	153	2.2	0.1	0.0	0.0	-0.2	0.1	0.1	2.6
SCH and RRC	154	2.1	0.0	0.1	0.5	-0.1	0.0	0.0	2.2
MDH and RRC	27	2.2	0.0	0.0	0.7	-0.2	0.1	0.0	2.2
Type of Ownership:									
Voluntary	1,881	2.5	0.0	-0.1	0.1	0.0	0.2	0.1	2.6
Proprietary	828	2.5	0.0	0.1	-0.1	0.1	0.1	0.1	2.6
Government	486	2.4	0.0	0.2	-0.3	-0.1	0.0	0.0	2.5
Medicare Utilization as a Percent of Inpatient Days:									
0-25	643	2.5	0.0	0.1	-0.6	-0.2	0.0	0.0	2.5
25-50	2,110	2.5	0.0	0.0	0.1	0.0	0.2	0.1	2.6
50-65	367	2.4	0.0	-0.1	0.2	0.3	0.3	0.2	2.2
Over 65	50	2.3	0.1	0.3	-0.7	-0.3	0.3	0.1	3.7
FY 2022 Reclassifications:									
All Reclassified Hospitals	934	2.4	0.0	0.0	1.2	-0.3	0.1	0.1	2.6
Non-Reclassified Hospitals	2,261	2.5	0.0	0.0	-0.9	0.2	0.2	0.2	2.6
Urban Hospitals Reclassified	749	2.4	0.0	0.0	1.1	-0.3	0.1	0.1	2.5
Urban Non-Reclassified Hospitals	1,723	2.5	0.0	0.0	-1.1	0.3	0.3	0.1	2.6
Rural Hospitals Reclassified Full Year	300	2.2	0.1	0.2	2.0	-0.2	0.0	0.0	2.5
Rural Non-Reclassified Hospitals Full Year	423	2.2	0.1	0.2	0.0	-0.2	0.0	0.2	3.3
All Section 401 Reclassified Hospitals	532	2.4	0.0	0.0	0.8	-0.3	0.1	0.1	2.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	2.3	0.1	0.0	2.4	-0.3	0.2	0.0	3.1

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2019, and hospital cost report data are from reporting periods beginning in FY 2018 and FY 2017.

[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 2.0 percent update to the national standardized amount and the hospital-specific rate (the estimated 2.7 percent market basket update reduced by 0.7 percentage point for the productivity adjustment), and the 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the changes to the Version 39 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2019 MedPAR data as the best available data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 1.000107 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2018 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000712.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2022 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2022. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.986737.

[6] This column displays the effects of the rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is 0.992868.

[6] This column displays the effects of the imputed rural floor for all-urban states provided for under section 1886(d)(3)(E)(iv) of the Act. This is not a budget neutral policy.

[8] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[9] This column shows the estimated change in payments from FY 2021 to FY 2022. This column includes the effects of the continued policy of increasing the wage index for hospitals with a wage index value below the 25th percentile wage index (that is, the lowest quartile wage index adjustment), the extended transition policy to place a 5-percent cap on any decrease in a hospital's wage index from its final wage index in FY 2021 (that is, the 5-percent cap), and the associated budget neutrality factors. This column reflects the budget neutrality factor of 0.998035 for the lowest quartile wage index adjustment and the budget neutrality factor of 0.99987 for the 5-percent cap for FY 2022.

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a. Effects of the Hospital Update and Other Adjustments (Column 1)

As discussed in section V.A. of the preamble of this final rule, this column includes the hospital update, including the 2.7 percent market basket update reduced by the 0.7 percentage point for the productivity adjustment. In addition, as discussed in section II.D. of the preamble of this final rule, this column includes the FY 2022 +0.5 percentage point adjustment required under section 414 of the MACRA. As a result, we make a 2.5 percent update to the national standardized amount. This column also includes the update to the hospital-specific rates which includes the 2.7 percent market basket update reduced by the 0.7 percentage point for the productivity adjustment. As a result, we are making a 2.0 percent update to the hospital-specific rates.

Overall, hospitals will experience a 2.5 percent increase in payments primarily due to the combined effects of the hospital update to the national standardized amount and the hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate would experience a 2.0 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate would experience a lower than average increase in payments.

b. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this final rule, the FY 2022 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2022, we are calculating the MS–DRGs using the FY 2019 MedPAR data grouped to the Version 39 (FY 2022) MS–DRGs. The methodology to calculate the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this final rule.

The ''All Hospitals'' line in Column 2 indicates that changes due to the MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 1.000107 to the standardized amount.

c. Effects of the Wage Index Changes (Column 3)

Column 3 shows the impact of the updated wage data using FY 2018 cost report data, with the application of the wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2022 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin Nos. 15–01, 17–01, and 18–04. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations, based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index, to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913) for a discussion of our adoption of the CBSA updates in OMB Bulletin No. 15–01, which were effective beginning with the FY 2017 wage index, to the FY 2020 IPPS/LTCH PPS final rule (83 FR 41362) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 17–01 for the FY 2020 wage index, and to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 18–04 for the FY 2021 wage index.

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2022 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2017 and before October 1, 2018. The estimated impact of the updated wage data using the FY 2018 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2021 wage index, based on FY 2017 wage data, the labor-related share of 68.3 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2022 pre-reclassification wage index based on FY 2018 wage data with the labor-related share of 67.6 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the Version 39 MS–DRG GROUPER constant. The FY 2022 occupational mix adjustment is based on the CY 2019 occupational mix survey.

In addition, the column shows the impact of the application of the wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2022, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 67.6 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The FY 2022 wage budget neutrality factor is 1.000712 and the overall payment change is 0 percent.

Column 3 shows the impacts of updating the wage data using FY 2018 cost reports. Overall, the new wage data and the labor-related share, combined with the wage budget neutrality adjustment, will lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage would increase 3.0 percent compared to FY 2021. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the 3.0 percent increase in the national average hourly wage. Of the 3,163 hospitals with wage data for both FYs 2021 and 2022, 1,578 or 50 percent would experience an average hourly wage increase of 3.0 percent or more.

The following chart compares the shifts in wage index values for hospitals due to changes in the average hourly wage data for FY 2022 relative to FY 2021. These figures reflect changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this final rule, which are available via the internet on the CMS website) is used to adjust the labor-related share of a hospital's standardized amount, either 67.6 percent (as proposed and finalized) or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the area wage index values for urban and rural hospitals.

FY 2022 Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase 10 percent or more	10	0
Increase greater than or equal to 5 percent and less than 10 percent	30	49
Increase or decrease less than 5 percent	2,372	667
Decrease greater than or equal to 5 percent and less than 10 percent	32	2
Decrease 10 percent or more	1	0
Unchanged	0	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2022.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials by the MGCRB of reclassification requests to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year (we refer readers to the discussion of our clarification of this policy in section III.I.2. of the preamble to this final rule.)

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are applying an adjustment of 0.986737 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this final rule).

As discussed elsewhere in this final rule, after a review of the public comments received on the interim final rule with comment period titled ''Medicare Program; Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board (MGCRB)'' (CMS–1762–IFC), we are finalizing those policies. Because these are MGCRB policies, the redistributional impacts of these policies in FY 2022 are included in Column 4 and they are taken into account in the calculation of the budget neutrality adjustment to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral.

Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.3 percent. By region, most rural hospital categories would experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website reflects the reclassifications for FY 2022.

e. Effects of the Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011 through 2021 IPPS/LTCH PPS final rules, and this FY 2022 IPPS/LTCH PPS final rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same State. We apply a uniform budget neutrality adjustment to the wage index. Column 5 shows the effects of the rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a FY 2022 rural floor budget neutrality factor to be applied to the wage index of 0.992868, which would reduce wage indexes by approximately 0.7 percent.

Column 5 shows the projected impact of the rural floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the post-reclassification FY 2022 wage index of providers before the rural floor adjustment and the post-reclassification FY 2022 wage index of providers with the rural floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural floor. Because the provision is budget neutral, all other hospitals that do not receive an increase to their wage index from the rural floor adjustment (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the budget neutrality adjustment that is applied to the wage index nationally. (As finalized in the FY 2020 IPPS/LTCH PPS final rule, we calculate the rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103.)

We estimate that 269 hospitals would receive the rural floor in FY 2022. All IPPS hospitals in our model would have their wage indexes reduced by the rural floor budget neutrality adjustment of 0.992868. We project that, in aggregate, rural hospitals would experience a 0.2 percent decrease in payments as a result of the application of the rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project that, in the aggregate, hospitals located in urban areas would experience no change in payments because increases in payments to hospitals benefitting from the rural floor offset decreases in payments to nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 3.7 percent increase in payments primarily due to the application of the rural floor in Massachusetts.

f. Effects of the Imputed Floor

As discussed in section III.X. of this rule, section 9831 of Public Law 117–2 established a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Thus, effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstates the imputed floor wage index policy for all-urban States, with no expiration date.

Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index is not applied in a budget neutral manner. Therefore, for FY 2022, the imputed floor adjustment is not budget neutral and would increase payments overall by approximately 0.2 percent compared to the provision not being in effect.

Column 6 shows the projected impact of the imputed floor adjustment applied to the wage index based on the OMB labor market area delineations. The column compares the post-reclassification FY 2022 wage index of providers after the rural floor adjustment and the post reclassification FY 2022 wage index of providers with the imputed floor adjustment.

There are an estimated 69 providers that will receive the imputed floor wage index

adjustment in FY 2022. This adjustment is not budget neutral, and we estimate the impact of the application of the imputed floor will be approximately $195 million.

g. Effects of the Application of the Frontier State Wage Index and Out-Migration Adjustment (Column 7)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and would increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and an estimated 44 hospitals located in those States would receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $64 million.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment would receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 245 providers that will receive the out-migration wage adjustment in FY 2022. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase will be approximately $55 million.

h. Effects of All FY 2022 Changes (Column 8)

Column 7 shows our estimate of the changes in payments per discharge from FY 2021 and FY 2022, resulting from all changes reflected in this final rule for FY 2022. It includes combined effects of the year-to-year change of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 2.6 percent for FY 2022 relative to FY 2021 and for this row is primarily driven by the changes reflected in Column 1. Column 7 includes the annual hospital update of 2.5 percent to the national standardized amount. This annual hospital update includes the 2.7 percent market basket update reduced by the 0.7 percentage point productivity adjustment. As discussed in section II.D. of the preamble of this final rule, this column also includes the +0.5 percentage point adjustment required under section 414 of the MACRA. Hospitals paid under the hospital-specific rate would receive a 2.0 percent hospital update. As described in Column 1, the annual hospital update with the +0.5 percent adjustment for hospitals paid under the national standardized amount, combined with the annual hospital update for hospitals paid under the hospital-specific rates, will result in a 2.6 percent increase in payments in FY 2022 relative to FY 2021. Column 8 also includes the effects of the continued policy to increase the wage index for hospitals with a wage index value below the 25th percentile wage index (that is, the lowest quartile wage index adjustment), the extended transition policy to place a 5-percent cap on any decrease in a hospital's wage index from its final wage index in FY 2021 (that is, the 5-percent cap), and the associated budget neutrality factors as discussed in section III.K.3. of the preamble of this final rule. There are interactive effects among the various factors comprising the payment system that we are not able to isolate, which contribute to our estimate of the changes in payments per discharge from FY 2021 and FY 2022 in Column 8.

Overall payments to hospitals paid under the IPPS due to the applicable percentage increase and changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 2.6 percent for FY 2022. Hospitals in urban areas will experience a 2.6 percent increase in payments per discharge in FY 2022 compared to FY 2021. Hospital payments per discharge in rural areas are estimated to increase by 2.8 percent in FY 2022.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2022 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2021 with the estimated average payments per discharge for FY 2022, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

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TABLE II.--IMPACT ANALYSIS OF CHANGES FOR FY 2022 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals (1)	Estimated Average FY 2021 Payment Per Discharge (2)	Estimated Average FY 2022 Payment Per Discharge (3)	FY 2022 Changes (4)
All Hospitals	3,195	13,109	13,448	2.6
By Geographic Location:				
Urban hospitals	2,459	13,454	13,800	2.6
Rural hospitals	736	9,901	10,178	2.8
Bed Size (Urban):				
0-99 beds	634	10,723	11,011	2.7
100-199 beds	754	11,015	11,305	2.6
200-299 beds	427	12,251	12,551	2.4
300-499 beds	421	13,496	13,847	2.6
500 or more beds	223	16,568	16,992	2.6
Bed Size (Rural):				
0-49 beds	311	8,556	8,921	4.3
50-99 beds	253	9,419	9,644	2.4
100-149 beds	94	9,789	10,033	2.5
150-199 beds	39	10,519	10,788	2.6
200 or more beds	39	11,465	11,784	2.8
Urban by Region:				
New England	112	14,858	15,254	2.7
Middle Atlantic	304	15,432	15,814	2.5
East North Central	381	12,838	13,150	2.4
West North Central	160	13,121	13,475	2.7
South Atlantic	402	11,710	12,050	2.9
East South Central	144	11,290	11,576	2.5
West South Central	364	11,806	12,072	2.3
Mountain	172	13,698	14,052	2.6
Pacific	370	17,230	17,665	2.5
Puerto Rico	50	8,491	8,638	1.7
Rural by Region:				
New England	19	13,990	14,463	3.4
Middle Atlantic	50	9,736	9,988	2.6
East North Central	113	10,361	10,592	2.2
West North Central	89	10,638	10,932	2.8
South Atlantic	114	9,032	9,302	3
East South Central	144	8,732	8,955	2.6
West South Central	135	8,292	8,540	3
Mountain	48	12,134	12,359	1.9
Pacific	24	13,865	14,588	5.2
By Payment Classification:				
Urban hospitals	1,983	12,673	13,003	2.6
Rural areas	1,212	13,796	14,148	2.6
Teaching Status:				
Nonteaching	2,031	10,677	10,963	2.7
Fewer than 100 residents	907	12,388	12,694	2.5
100 or more residents	257	18,938	19,437	2.6
Urban DSH:				
Non-DSH	502	11,749	12,054	2.6
100 or more beds	1,227	13,015	13,355	2.6

	Number of Hospitals (1)	Estimated Average FY 2021 Payment Per Discharge (2)	Estimated Average FY 2022 Payment Per Discharge (3)	FY 2022 Changes (4)
Less than 100 beds	348	9,559	9,820	2.7
Rural DSH:				
SCH	265	11,906	12,203	2.5
RRC	608	14,380	14,748	2.6
100 or more beds	30	12,115	12,298	1.5
Less than 100 beds	215	7,778	8,026	3.2
Urban teaching and DSH:				
Both teaching and DSH	679	14,116	14,483	2.6
Teaching and no DSH	74	12,825	13,127	2.4
No teaching and DSH	896	10,850	11,137	2.6
No teaching and no DSH	334	10,824	11,109	2.6
Special Hospital Types:				
RRC	523	14,478	14,859	2.6
SCH	305	12,053	12,356	2.5
MDH	153	9,169	9,405	2.6
SCH and RRC	154	12,475	12,746	2.2
MDH and RRC	27	10,622	10,853	2.2
Type of Ownership:				
Voluntary	1,881	13,321	13,667	2.6
Proprietary	828	11,473	11,769	2.6
Government	486	14,109	14,466	2.5
Medicare Utilization as a Percent of Inpatient Days:				
0-25	643	15,158	15,535	2.5
25-50	2,110	12,926	13,268	2.6
50-65	367	10,773	11,011	2.2
Over 65	50	8,132	8,431	3.7
FY 2022 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	934	13,592	13,944	2.6
Non-Reclassified Hospitals	2,261	12,772	13,102	2.6
Urban Hospitals Reclassified	749	14,261	14,619	2.5
Urban Nonreclassified Hospitals	1,723	12,851	13,187	2.6
Rural Hospitals Reclassified Full Year	300	10,087	10,341	2.5
Rural Nonreclassified Hospitals Full Year	423	9,610	9,929	3.3
All Section 401 Reclassified Hospitals:	532	14,968	15,343	2.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	9,149	9,430	3.1

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H. Effects of Other Policy Changes

In addition to those policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. As noted in section I.G. of this Appendix A, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes using that payment simulation model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other changes are discussed in this section.

1. Effects of Policies Relating to New Medical Service and Technology Add-On Payments and New COVID–19 Treatments Add-on Payment (NCTAP)

a. FY 2022 Status of Technologies Approved for FY 2021 New Technology Add-On Payments

In section II.F.4. of the preamble of this final rule, as proposed we are continuing to make new technology add-on payments for AZEDRA®, BAROSTIM NEO System, BALVERSA™, Jakafi®, FETROJA®, Optimizer® System, RECARBRIO™, Soliris®, XENLETA™, and ZERBAXA® in FY 2022 because these technologies would still be considered new for purposes of new technology add-on payments. We are also finalizing a 1-year extension for FY 2022 of the new technology add-on payments for the following technologies, for which new technology add-on payments would otherwise be discontinued beginning with FY 2022: AndexXa™, Cablivi®, ContaCT, Eluvia Drug-Eluting Vascular Stent System, ELZONRIS®, Esketamine (SPRAVATO®), Hemospray, IMFINZI/TECENTRIQ, NUZYRA, Spinejack, T2 Bacteria Test Panel, XOSPATA®, and ZEMDRI™. We refer

readers to section II.F. of the preamble of this final rule with regard to our finalization of this 1-year extension of new technology add-on payments for these technologies in FY 2022.

Under § 412.88(a)(2), the new technology add-on payment for each case would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as Qualified Infectious Disease Products (QIDPs) or approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs or approved under the LPAD pathway). Because it is difficult to predict the actual new technology add-on payment for each case, our estimates in this final rule are based on applicant's estimate at the time they submitted their original application and the increase in new technology add-on payments for FY 2022 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. In the following table are estimates for the 23 technologies for which we are continuing to make new technology add-on payments in FY 2022:

Technology Name	Estimated Cases	FY 2022 NTAP amount (65 % or 75 %)	Estimated Total FY 2022 Impact
Andexa Xa	5,402	$18,281.25	$98,755,312.50
Azedra	400	$98,150.00	$39,260,000.00
BAROSTIM NEO System	722	$22,750.00	$16,425,500.00
Caplacizumab	131	$33,215.00	$4,351,165.00
ContaCT	69,336	$1,040.00	$72,109,440.00
Erdafitinib (Balversa)	50	$3,563.23	$178,161.50
Esketamine (SPRAVATO)	6,400	$1,014.79	$6,494,656.00
Eluvia Drug-Eluting Vascular Stent System	2,453	$3,646.50	$8,944,864.50
Elzonris	247	$144,116.04	$35,596,661.88
FETROJA	6,355	$7,919.86	$50,330,710.30
Hemospray	12,700	$1,625.00	$20,637,500.00
IMFINZI/TECENTRIQ	4,296	$6,875.90	$29,538,866.40
Jakafi	140	$4,475.38	$626,553.20
NUZYRA	16,899	$1,552.50	$26,235,697.50
Optimizer System	1,500	$14,950.00	$22,425,000.00
RECARBRIO	762	$3,532.78	$2,691,978.36
Soliris	13,680	$21,199.75	$290,012,580.00
Spinejack	1,572	$3,654.72	$5,745,219.84
T2 Bacteria Test Panel	37639	$97.50	$3,669,802.50
XENLETA	35246	$1,275.75	$44,965,084.50
Xospata	1,875	$7,312.50	$13,710,937.50
ZERBAXA	30,117	$1,836.98	$55,324,326.66
Zemdri	2,500	$4,083.75	$10,209,375.00

b. FY 2022 Applications for New Technology Add-On Payments

In sections II.F.5. and 6. of the preamble to this final rule, we discussed 43 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2022. We note that 5 applicants withdrew their application prior to the issuance of the proposed rule. We further note that 7 applicants withdrew their application prior to the issuance of the final rule, and 3 applicants did not meet the July 1, 2021 deadline for FDA marketing authorization. As explained in the preamble to this final rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.F.6. of the preamble of this final rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation, approved through the FDA LPAD pathway, or are part of the Breakthrough Device program will be considered new and not substantially similar to an existing technology and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still meet the cost criterion.

As also discussed in section II.F.6. of the preamble of this final rule, we are approving or conditionally approving 10 alternative pathway applications for FY 2022 new technology add-on payments. Based on information from the applicants at the time of rulemaking, we estimate that total payments for the 10 technologies that we are approving or conditionally approving under the alternative pathway would be approximately $151 million for FY 2022. Total estimated FY 2022 payments for new technologies that are designated as a QIDP would be approximately $50 million, and total estimated FY 2022 payments for new technologies that are part of the Breakthrough Device program will be approximately $101 million. In the following table are estimates for the 10 technologies for which we are approving new technology add-on payments under the alternative pathway in FY 2022:

Technology Name	Estimated Cases	FY 2022 NTAP amount (65 % or 75 %)	Estimated Total FY 2022 Impact	Pathway (QIDP, LPAD, or Breakthrough Device)
Ascope duodeno	3,750	$1,715.58	$6,433,425	Breakthrough Device
Aprevo	1,261	$40,950.00	$51,637,950	Breakthrough Device
Caption Guidance	2,592	$1,868.10	$4,842,115.20	Breakthrough Device
Contepo	17,320	$2,275.00	$39,403,000.00	QIDP
Exalt Model D	8,314	$1,715.58	$14,236,332.12	Breakthrough Device
Fetroja	379	$7,435.86	$2,818,190.94	QIDP
Harmony TPV	171	$26,975.00	$4,612,725.00	Breakthrough Device
PRCFC	2,296	$2,535.00	$5,820,360.00	Breakthrough Device
Recarbrio	928	$8,299.64	$7,702,065.92	QIDP
Shockwave Coronary IVL	3,760	$3,666.00	$13,784,160.00	Breakthrough Device

As discussed in section II.F.5. of the preamble of this final rule, we are approving 7 technologies under the traditional pathway for new technology add-on payments for FY 2022. Based on information from the applicants at the time of rulemaking, we estimate that total payments for the 7 technologies that we are approving under the traditional pathway would be approximately $498 million for FY 2022. In the following table are estimates for the 7 technologies for which we are approving new technology add-on payments under the traditional pathway in FY 2022:

Technology Name	Estimated Cases	FY 2022 NTAP amount (65 % or 75 %)	Estimated Total FY 2022 Impact
Rybrevant	349	$6,405.89	$2,235,655.61
Abecma	179	$242,450.00	$43,398,550.00
Stratagraft	261	$44,200.00	$11,536,200.00
Tecartus	15	$242,450.00	$3,636,750.00
Trilaciclib	435	$5,526.30	$2,403,940.50
Veklury	174,996	$2,028.00	$354,891,888.00
Zepzelca	778	$8,622.90	$6,708,616.20

c. Changes to FY 2022 New COVID–19 Treatments Add-On Payment (NCTAP)

As discussed in section II.F. of the preamble of this final rule, in response to the COVID–19 PHE, we established the NCTAP under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71157 and 71158). In this final rule, we are finalizing to extend the NCTAP through the end of the fiscal year in which the PHE ends for all eligible products, including those approved for new technology add-on payments for FY 2022.

Given that it is unknown what the cost and utilization of inpatient stays using these new treatments will be, the net overall cost of the extension of the NCTAP is not estimable. On one extreme, if all of the new COVID–19 treatments decrease the net cost of hospitalizations (for example, due to shortened lengths of stay), including the cost of the new treatment, below the Medicare payment for discharges after the end of the PHE and through the end of the fiscal year in which the PHE ends, then there would be no NCTAP made and no additional cost to the Medicare program as a result of this extension. On the other extreme, if all of the new COVID–19 treatments result in the net cost of hospitalizations that exceed the outlier threshold (for example, due to the cost of the new treatment) for discharges after the end of the PHE and through the end of the fiscal year in which the PHE ends, the cost to the Medicare program would be the sum over all such NCTAP cases of 0.65 times the outlier threshold for each case.

2. Effects of the Changes to Medicare DSH and Uncompensated Care Payments for FY 2022

As discussed in section V.E. of the preamble of this final rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals and any additional statutory adjustment (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this final rule, as we proposed, we are establishing the amount to be distributed as uncompensated care payments to DSH eligible hospitals for FY 2022. The final estimate of the amount available to make uncompensated care payments is $7,192,008,709.70. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 68.57 percent. For FY 2021, the amount available to be distributed for uncompensated care was $8,290,014,520.96 or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 72.86 percent. Consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule for FY 2022 and subsequent fiscal years, we are using a single year of data on uncompensated care costs from Worksheet S–10 of the FY 2018 cost reports to calculate Factor 3 in the FY 2022 methodology for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico Hospitals. To calculate Factor 3 for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we are using data regarding Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available SSI days (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data). For a complete discussion of the methodology for

calculating Factor 3, we refer readers to section V.E.4. of the preamble of this final rule.

To estimate the impact of the combined effect of the changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare uncompensated care payments, we compared total uncompensated care payments estimated in the FY 2021 IPPS/LTCH PPS final rule to total uncompensated care payments estimated in this FY 2022 IPPS/LTCH PPS final rule. For FY 2021, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 72.86 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2021 IPPS/LTCH PPS final rule. For FY 2022, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments during FY 2022 absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 68.57 percent and multiplied by a Factor 3 calculated using the methodology described previously.

Our analysis included 2,366 hospitals that are projected to be eligible for DSH in FY 2022. It did not include hospitals that had terminated their participation in the Medicare program as of June 28, 2021, Maryland hospitals, new hospitals, MDHs, and SCHs that are expected to be paid based on their hospital-specific rates. The 26 hospitals participating in the Rural Community Hospital Demonstration Program were excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the non surviving CCN was excluded from the analysis. The estimated impact of the changes in Factors 1, 2, and 3 on uncompensated care payments across all hospitals projected to be eligible for DSH payments in FY 2022, by hospital characteristic, is presented in the following table.

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Modeled Uncompensated Care Payments for Estimated FY 2022 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2021 to FY 2022					
	Number of Estimated DSHs (1)	FY 2021 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2022 Final Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2021 - FY 2022 ($ in millions) (4)	Percent Change** (5)
Total	**2,366**	**$8,290**	**$7,192**	**-$1,098**	**-13.24%**
By Geographic Location					
Urban Hospitals	1,901	7803	6789	-1,014	-13.00
Large Urban Areas	989	4829	4143	-686	-14.21
Other Urban Areas	912	2974	2646	-328	-11.03
Rural Hospitals	465	487	403	-84	-17.22
Bed Size (Urban)					
0 to 99 Beds	325	290	245	-45	-15.43
100 to 249 Beds	819	1898	1603	-295	-15.54
250+ Beds	757	5615	4941	-674	-12.01
Bed Size (Rural)					
0 to 99 Beds	352	269	218	-51	-18.91
100 to 249 Beds	100	166	141	-26	-15.46
250+ Beds	13	52	45	-7	-14.09
Urban by Region					
New England	92	227	187	-40	-17.73
Middle Atlantic	231	983	820	-163	-16.55
South Atlantic	313	864	801	-63	-7.3
East North Central	98	405	354	-51	-12.51
East South Central	312	2,027	1,756	-271	-13.37
West North Central	126	498	439	-59	-11.85
West South Central	241	1,637	1,433	-204	-12.49
Mountain	132	333	299	-34	-10.25
Pacific	315	723	608	-115	-15.93
Puerto Rico	41	107	93	-14	-13.01
Rural by Region					
New England	8	15	15	0	-1.19
Middle Atlantic	21	15	12	-3	-17.85
South Atlantic	65	58	43	-15	-25.23
East North Central	28	31	23	-8	-25.82
East South Central	83	135	117	-17	-12.94
West North Central	124	102	85	-18	-17.15
West South Central	107	105	88	-17	-15.86
Mountain	24	19	14	-5	-25.88
Pacific	5	7	5	-2	-25.64
By Payment Classification					
Urban Hospitals	1,507	5,470	4,774	-696	-12.72
Large Urban Areas	850	3,614	3,125	-489	-13.54
Other Urban Areas	657	1,855	1,649	-206	-11.12
Rural Hospitals	859	2,820	2,418	-402	-14.27
Teaching Status					
Nonteaching	1,371	2,444	2,118	-326	-13.34
Fewer than 100 residents	742	2,865	2,492	-373	-13.02
100 or more residents	253	2,980	2,582	-399	-13.39

Modeled Uncompensated Care Payments for Estimated FY 2022 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2021 to FY 2022

	Number of Estimated DSHs (1)	FY 2021 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2022 Final Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2021 - FY 2022 ($ in millions) (4)	Percent Change** (5)
Type of Ownership					
Voluntary	1,423	4,556	3,981	-575	-12.62
Proprietary	575	1,217	1,077	-140	-11.5
Government	368	2,517	2,134	-383	-15.22
Medicare Utilization Percent***					
0 to 25	554	3,388	2,941	-447	-13.19
25 to 50	1,603	4,707	4,097	-610	-12.96
50 to 65	187	189	150	-39	-20.79
Greater than 65	22	6	4	-2	-32.81

Source: Dobson | DaVanzo analysis of 2013 and 2018 Hospital Cost Reports.

*Dollar uncompensated care payments calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments are estimated to be $8,290 million in FY 2021 and $7,192 million in FY 2022.

** Percentage change is determined as the difference between Medicare uncompensated care payments modeled for this FY 2022 IPPS/LTCH PPS final rule (column 3) and Medicare uncompensated care payments modeled for the FY 2021 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare uncompensated care payments modeled for the FY 2021 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

***Hospitals with missing or unknown Medicare utilization are not shown in table.

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The changes in projected FY 2022 uncompensated care payments from payments in FY 2021 are driven by a decrease in Factor 1 and a decrease in Factor 2, as well as by a decrease in the number of hospitals projected to be eligible to receive DSH in FY 2022 relative to FY 2021. Factor 1 has decreased from the FY 2021 final rule's Factor 1 of $11.378 billion to this FY 2022 final rule's Factor 1 of $10.489 billion, while the percent change in the percent of individuals who are uninsured (Factor 2) has decreased from 72.86 percent to 68.57 percent. Based on the changes in these two factors, the impact analysis found that, across all projected DSH eligible hospitals, FY 2022 uncompensated care payments are estimated at approximately $7.192 billion, or a decrease of approximately 13.24 percent from FY 2021 uncompensated care payments (approximately $8.290 billion). While these changes will result in a net decrease in the amount available to be distributed in uncompensated care payments, the projected payment decreases vary by hospital type. This redistribution of uncompensated care payments is caused by changes in Factor 3. As seen in the previous table, a percent change of less than negative 13.24 percent indicates that hospitals within the specified category are projected to experience a larger decrease in uncompensated care payments, on average, compared to the universe of projected FY 2022 DSH hospitals. Conversely, a percent change greater than negative 13.24 percent indicates that a hospital type is projected to have a smaller decrease than the overall average. The variation in the distribution of payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported in the Worksheet S–10, or number of Medicaid days and SSI days for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, used in the Factor 3 computation.

Rural hospitals, in general, are projected to experience larger decreases in uncompensated care payments than their urban counterparts. Overall, rural hospitals are projected to receive a 17.22 percent decrease in uncompensated care payments, which is a greater decrease than the overall hospital average, while urban hospitals are projected to receive a 13.00 percent decrease in uncompensated care payments, similar to the overall hospital average.

By bed size, smaller rural hospitals are projected to receive the largest decreases in uncompensated care payments. Rural hospitals with 0–99 beds are projected to receive an 18.91 percent payment decrease, and rural hospitals with 100–249 beds are projected to receive a 15.46 percent decrease. In contrast, larger rural hospitals with 250+ beds are projected to receive a 14.09 percent payment decrease. Among urban hospitals, the smallest urban hospitals, those with 0–99 and 100–249 beds, are projected to receive a decrease in uncompensated care payments that is greater than the overall hospital average, at 15.43 and 15.54 percent, respectively. In contrast, the largest urban hospitals with 250+ beds are projected to receive a 12.01 percent decrease in uncompensated care payments, which is a smaller decrease than the overall hospital average.

By region, rural hospitals are expected to receive larger than average decreases in uncompensated care payments in all Regions, except for rural hospitals in New England, which are projected to receive a decrease of 1.19 percent in uncompensated care payments, and rural hospitals in the East South Central Region, which are projected to receive a smaller than average decrease of 12.94 percent. Regionally, urban hospitals are projected to receive a more varied range of payment changes. Urban hospitals in the New England, Middle Atlantic, East South Central, and Pacific Regions are projected to receive larger than average decreases in uncompensated care payments. Urban hospitals in the South Atlantic, East North Central, West North Central, West South Central, and Mountain Regions, as well as hospitals in Puerto Rico are projected to receive smaller than average decreases in uncompensated care payments.

By payment classification, although hospitals in urban areas overall are expected to receive a 12.72 percent decrease in uncompensated care payments, hospitals in large urban areas are expected to see a decrease in uncompensated care payments of 13.54 percent, while hospitals in other urban areas are expected to receive a decrease in uncompensated care payments of 11.12 percent. Rural hospitals are projected to receive the largest decrease of 14.27 percent.

Nonteaching hospitals are projected to receive a payment decrease of 13.34 percent, teaching hospitals with fewer than 100 residents are projected to receive a payment decrease of 13.02 percent, and teaching hospitals with 100+ residents have a projected payment decrease of 13.39 percent. All of these decreases closely approximate the overall hospital average. Proprietary and voluntary hospitals are projected to receive smaller than average decreases of 11.50 and 12.62 percent respectively, while government hospitals are expected to receive a larger payment decrease of 15.22 percent. All

hospitals with less than 50 percent Medicare utilization are projected to receive decreases in uncompensated care payments consistent with the overall hospital average percent change, while hospitals with 50–65 percent and greater than 65 percent Medicare utilization are projected to receive larger decreases of 20.79 and 32.81 percent, respectively.

3. Effects of Reductions Under the Hospital Readmissions Reduction Program for FY 2022

In section V.G. of the preamble of this final rule, we discuss our policies for the FY 2022 Hospital Readmissions Reduction Program. This program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions and procedures. The table and analysis in this final rule illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25758 through 25760), for the purpose of modeling the FY 2022 payment adjustment factors, we used the payment adjustment factors from the FY 2021 Hospital Readmissions Reduction Program and the FY 2021 Hospital IPPS final rule Impact File to analyze results by hospital characteristics. In this final rule, we are updating the estimated financial impact using the estimated payment adjustment factors from the FY 2022 Hospital Readmissions Reduction Program and the FY 2022 Hospital IPPS proposed rule Impact File to analyze results by hospital characteristics. Hospitals are stratified into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2017 and December 1, 2019 (that is, the data period used for the FY 2022 Hospital Readmissions Reduction Program). Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. In this FY 2022 IPPS/LTCH PPS final rule, we provide an updated estimate of the financial impact using the proportion of dually-eligible beneficiaries, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2022 Hospital Readmissions Reduction Program applicable period. We note that for the FY 2022 applicable period, we will only be assessing data from July 1, 2017 through December 1, 2019 due to the COVID–19 public health emergency (PHE) nationwide Extraordinary Circumstance Exception (ECE) which excluded data from January 1, 2020 through June 30, 2020 from the Hospital Readmissions Reduction Program calculations.[1391]

The results in the table include 2,938 non-Maryland hospitals eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2017 and December 1, 2019. The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The third column in the table indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 82.16 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 88.94 percent of eligible hospitals with fewer than 100 residents and 93.33 percent of eligible hospitals with 100 or more residents are expected to be penalized.

The fourth column in the table estimates the financial impact on hospitals by hospital characteristic. The table shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between January 1, 2019 and December 31, 2019 (CY 2019). For example, the penalty as a share of payments for urban hospitals is 0.63 percent. This means that total penalties for all urban hospitals are 0.63 percent of total payments for urban hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

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[1391] Although the FY 2022 applicable period is July 1, 2017 through June 30, 2020, we note that first and second quarter data from CY 2020 is excluded from consideration for calculations purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for identifying index stays will be adjusted to July 1, 2017 through December 1, 2019. Further information will be found in the FY 2022 Hospital Specific Report (HSR) User Guide located on QualityNet website at: *https://qualitynet.cms.gov/inpatient/hrrp/reports* that is anticipated to become available in August 2021.

Estimated Percentage of Hospitals Penalized and Penalty as Share of Payments for FY 2022 Hospital Readmissions Reduction Program by Hospital Characteristic				
Hospital Characteristic	**Number of Eligible Hospitals[a]**	**Number of Penalized Hospitals[b]**	**Percentage of Hospitals Penalized[c] (%)**	**Penalty as a Share of Payments[d] (%)**
All Hospitals	2,938	2,500	85.09	0.63
By Geographic Location (n=2,938)				
Urban hospitals	2,226	1,920	86.25	0.63
1-99 beds	504	356	70.63	0.75
100-199 beds	688	620	90.12	0.79
200-299 beds	405	370	91.36	0.74
300-399 beds	271	249	91.88	0.64
400-499 beds	137	120	87.59	0.60
500 or more beds	221	205	92.76	0.47
Rural hospitals	712	580	81.46	0.65
1-49 beds	291	215	73.88	0.54
50-99 beds	251	209	83.27	0.62
100-149 beds	92	83	90.22	0.65
150-199 beds	39	35	89.74	0.64
200 or more beds	39	38	97.44	0.73
By Teaching Status[e] (n=2,938)				
Non-teaching	1,833	1,506	82.16	0.77
Fewer than 100 residents	850	756	88.94	0.65
100 or more residents	255	238	93.33	0.44
By Ownership Type (n=2,938)				
Government	443	365	82.39	0.54
Proprietary	725	593	81.79	0.90
Voluntary	1,770	1,542	87.12	0.59
By Safety-net Status[f] (n=2,938)				
Safety-net hospitals	578	496	85.81	0.52
Non-safety-net hospitals	2,360	2,004	84.92	0.66
By Disproportionate Share Hospital (DSH) Patient Percentage[g] (n= 2,938)				
0-24	1,199	974	81.23	0.73
25-49	1,415	1,246	88.06	0.59
50-64	185	167	90.27	0.59
65 and over	139	113	81.29	0.44
By Medicare Cost Report (MCR) Percentage[h,i] (n= 2,931)				
0-24	504	432	85.71	0.48
25-49	2,051	1,761	85.86	0.64
50-64	342	282	82.46	0.86
65 and over	34	22	64.71	0.86
By Region (n=2,938)				
New England	125	115	92.00	0.82
Middle Atlantic	329	302	91.79	0.64
East North Central	466	398	85.41	0.65
West North Central	236	184	77.97	0.40
South Atlantic	497	455	91.55	0.71
East South Central	269	245	91.08	0.77
West South Central	448	372	83.04	0.62
Mountain	219	153	69.86	0.56
Pacific	349	276	79.08	0.48

Source: The table results are based on the estimated FY 2022 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The FY 2022 payment adjustment factors are based on discharges between July 1, 2017

and December 1, 2019. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2021 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are stratified into five peer groups based on the proportion of FFS and managed care dual-eligible stays for the performance period. Hospital characteristics are from the FY 2022 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule Impact File.

For the FY 2022 applicable period, we will only be assessing data from July 1, 2017 through December 1, 2019 due to the COVID-19 public health emergency (PHE) nationwide Extraordinary Circumstances Exception (ECE) which excluded data from January 1, 2020 through June 30, 2020 from the Hospital Readmissions Reduction Program calculations. The discharge period in this report has been updated to reflect this ECE. The readmission measures used in the Hospital Readmissions Reduction Program identify readmissions within 30 days of each index stay; therefore, the performance periods for the measures end 30 days before January 1, 2020, on December 1, 2019, so that no claims from January 1, 2020 through June 30, 2020 are used in the measure or program calculations.

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).
[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.
[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.
[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. MedPAR data from January 1, 2019 through December 31, 2019 (CY 2019), are used to estimate the total base operating DRG payments.
[e] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.
[f] A hospital is considered a safety-net hospital if it is in the top DSH quintile.
[g] DSH [Disproportionate Share Hospital] patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.
[h] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals for MCR [Medicare Cost Report] percentage because not all hospitals have data for MCR percentage (n=2,929; missing=7).
[i] MCR percentage is the percentage of total inpatient stays from Medicare patients.

We did not receive any public comments regarding the impact of our proposals.

4. Effects of Changes Under the FY 2022 Hospital Value-Based Purchasing (VBP) Program

In section V.H. of the preamble of this final rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. We are finalizing our proposals to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, Medicare Spending Per Beneficiary (MSPB) and five healthcare-associated infection (HAI) measures, as well as changing the scoring and payment methodologies for the FY 2022 program year, such that all participating hospitals will receive a value-based incentive payment percentage that results in a value-based incentive payment amount that is equal to the applicable percentage (2 percent). Specifically, we will calculate the measure rates for all of the measures we have selected for the FY 2022 program year, but we will not generate achievement or improvement points for any of the measures we are suppressing. Additionally, we will not award domain scores for the Person and Community Engagement, Efficiency and Cost Reduction, and Safety domains. Therefore, we will not award hospitals a TPS, and will instead award hospitals a payment incentive multiplier that results in a value-based incentive payment amount that is equal to the amount withheld for the fiscal year (2 percent). That is, each hospital will receive a 2 percent reduction to its base operating DRG payment amount for each FY 2022 discharge and will then receive a value-based incentive payment percentage that will result in a value-based incentive payment amount that is equal to the 2 percent withheld. Under these finalized policies, the impact for every hospital under the Hospital VBP Program will be a net percentage payment adjustment of zero.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25760 through 25761), we also provided the estimated impact of the FY 2022 program because those impacts would apply if the proposals discussed previously were not finalized. However, because we are finalizing the policies as proposed, all adjustment factors for all hospitals will reflect a net-neutral payment adjustment for hospitals in accordance with the finalized FY 2022 special scoring policy at § 412.168.

We are also finalizing our proposal to suppress the MORT–30–PN measure for the FY 2023 program year. Under this finalized policy, we will calculate the measure rate for the MORT–30–PN program year. However, we will not generate achievement or improvement points for that measure. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25469 through 25496), we did not propose to suppress any other measures for the FY 2023 program year. We also did not propose any changes to the scoring methodology for the FY 2023 program in the proposed rule. Hospitals will still receive achievement and improvement points on the remaining measures for which they report the minimum number of cases, and they will receive scores on domains for which they report the minimum number of measures for the FY 2023 program year. The domain scores, weighted at 25 percent each, will be used to calculate TPSs for the FY 2023 program year. As discussed in section VI.H.3.c. of this final rule, we are also finalizing our proposal to remove the CMS PSI 90 measure beginning with the FY 2023 program year. However, because we are removing this measure before it would be used in calculating a hospital's TPS under the Hospital VBP Program, we do not expect this provision will have impacts for the FY 2023 program year.

We did not receive any public comments regarding the impact of our proposals.

5. Effects Under the HAC Reduction Program for FY 2022

We are presenting the estimated impact of the FY 2022 Hospital-Acquired Condition (HAC) Reduction Program on hospitals by hospital characteristic in the following table, Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2022 HAC

Reduction Program (by Hospital Characteristic). These estimated results were calculated using the Equal Measure Weights approach finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41486 through 41489). Each hospital's Total HAC Score was calculated as the equally weighted average of the hospital's measure scores. The table in this section presents the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic using the 1-year performance period for the HAI measures pursuant to the measure suppression policy discussed in section IX.I.3.d. of the preamble of this final rule and its adoption for the FY 2022 program year.

The table calculates hospitals' CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure results based on Medicare fee-for-service (FFS) discharges from July 1, 2018 through December 31, 2019 [1392] and version 11.0 of the PSI software. Hospitals' measure results for the Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) measures are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2019 and December 31, 2019.[1393]

The table includes 3,067 non-Maryland hospitals with a FY 2022 Total HAC Score. Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. The first column presents a breakdown of each characteristic and the second column indicates the number of hospitals for the respective characteristic.

The third column in the table indicates the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. These hospitals would receive a payment reduction under the FY 2022 HAC Reduction Program. For example, regarding teaching status, 426 hospitals out of 1,929 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 221 out of 875 hospitals with fewer than 100 residents and 117 out of 257 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the proportion of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2022 HAC Reduction Program. For example, 22.1 percent of the 1,929 hospitals characterized as non-teaching hospitals, 25.3 percent of the 875 teaching hospitals with fewer than 100 residents, and 45.5 percent of the 257 teaching hospitals with 100 or more residents would be subject to a payment reduction.

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[1392] As explained in section V.I.7., in memorandum released in March 2020, through application of our ECE policy, we excluded first and second quarter CY 2020 CMS PSI 90 data from FY 2022 Total HAC Scores. The resulting applicable period for the CMS PSI 90 measure in the FY 2022 HAC Reduction Program is the 18-month period from July 1, 2018 through December 31, 2019.

[1393] As explained in section V.I.7., in an interim final rule with comment period (IFC) published on September 2, 2020, through application of our ECE policy, we excluded first and second quarter CY 2020 CDC NHSN HAI data from FY 2022 Total HAC Scores. In section V.I.3.d. of the preamble of this final rule, we finalized the suppression of third and fourth quarter CY 2020 CDC NHSN HAI data from FY 2022 Total HAC Scores. The resulting applicable period for the CDC NHSN HAI measures in the FY 2022 HAC Reduction Program is the 12-month period from January 1, 2019 through December 31, 2019.

Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2022 HAC Reduction Program (by Hospital Characteristic)			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-performing Quartile[a]**	**Percent of Hospitals in the Worst-performing Quartile[b]**
Total[c]	3,067	766	25
By Geographic Location (n = 3,061)[d]			
Urban hospitals	**2,327**	**589**	**25.3**
1-99 beds	572	100	17.5
100-199 beds	704	191	27.1
200-299 beds	417	101	24.2
300-399 beds	273	69	25.3
400-499 beds	139	45	32.4
500 or more beds	222	83	37.4
Rural hospitals	**734**	**175**	**23.8**
1-49 beds	311	70	22.5
50-99 beds	252	63	25.0
100-149 beds	93	20	21.5
150-199 beds	39	11	28.2
200 or more beds	39	11	28.2
By Safety-Net Status[e] (n = 3,061)			
Non-safety net	2,442	564	23.1
Safety-net	619	200	32.3
By DSH Percent[f] (n = 3,061)			
0-24	1,270	265	20.9
25-49	1,438	377	26.2
50-64	194	64	33.0
65 and over	159	58	36.5
By Teaching Status[g] (n =3,061)			
Non-teaching	1,929	426	22.1
Fewer than 100 residents	875	221	25.3
100 or more residents	257	117	45.5
By Ownership (n = 3,061)			
Voluntary	1,818	477	26.2
Proprietary	773	136	17.6
Government	470	151	32.1
By MCR Percent[h] (n = 3,054)			
0-24	584	163	27.9
25-49	2,081	508	24.4
50-64	349	82	23.5
65 and over	40	6	15.0
By Region[i] (n= 3,067)			
New England	130	49	37.7
Mid-Atlantic	339	110	32.4
South Atlantic	507	132	26.0
East North Central	479	123	25.7
East South Central	282	68	24.1
West North Central	244	55	22.5
West South Central	476	80	16.8
Mountain	229	54	23.6
Pacific	381	95	24.9

Source: FY 2022 HAC Reduction Program final rule results are based on CMS PSI 90 data from July 1, 2018 through December 31, 2019 and CDC NHSN HAI results from January 1, 2019 through December 31, 2019. Hospital Characteristics are based on the FY 2022 Proposed Rule Impact File

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2022 Total HAC Score (N = 3,067). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, teaching status, and Ownership (n = 3,061).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for MCR percent (n = 3,054).

[i] All hospitals had data for Region (n = 3,067). For the 6 hospitals that were not in the FY 2022 Proposed Rule Impact File region data were identified using the hospital CCN.

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We did not receive any public comments regarding the impact of our proposals.

6. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2022

In section V.J. of the preamble of this final rule for FY 2022, we discussed our implementation and budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, by section 15003 of Public Law 114–255, and most recently, by section 128 of Public Law 116–260, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 128 of Public Law 116–255 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 15-year extension period (that is, for an additional 5 years beyond the current extension period). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019. We, therefore, interpret the statute as providing for an additional 5-year period under the reasonable cost-based reimbursement methodology for the demonstration for the hospitals that were participating as of this date.

Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality). We are adopting the general methodology used in previous years, whereby we estimate the additional payments made by the program for each of the participating hospitals as a result of the demonstration, and then adjust the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we apply budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For this final rule, the resulting amount applicable to FY 2022 is $65,779,803, which we are proposing to include in the budget neutrality offset adjustment for FY 2022. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and currently finalized update factors for cost and payment.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2015 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 128 of Public Law 116–260, we will continue this general procedure. All finalized cost reports are now available for the 18 hospitals that completed a cost reporting period beginning in FY 2016 according to the demonstration cost-based payment methodology. For this fiscal year, the actual costs of the demonstration as indicated by the finalized cost reports exceeded the estimated amount identified in the final rule for that year by $3,797,994. Keeping with previous practice, we are adding this difference to the estimated about for the upcoming year in arriving at the total budget neutrality offset amount for FY 2022. This amount is $69,577,797, which we will subtract from the national IPPS payment rates.

7. Effects of the Repeal of the Market-Based MS–DRG Policy

In section V.L. of the preamble of this final rule, we discuss the final policy to repeal the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021, as finalized in the FY 2021 IPPS/LTCH PPS final rule. In the FY 2021 IPPS/LTCH PPS final rule, we estimated the total annual burden hours for this data collection requirement as follows: 20 hours per hospital times 3,189 total hospitals equals 63,780 annual burden hours and $4,315,993 annually for all hospitals nationally. We refer readers to 85 FR 59015 for further analysis of this assessment.

The market-based MS–DRG relative weight methodology, as finalized in the FY 2021 IPPS/LTCH PPS final rule, was adopted effective beginning with the relative weights calculated for FY 2024. As discussed in section V.L of the preamble of this final rule, we are finalizing our proposal to repeal the market-based MS–DRG relative weight methodology effective in FY 2024. As such, we will continue calculating the MS–DRG relative weights using the current cost-based MS–DRG relative weight methodology for FY 2024 and subsequent fiscal years.

Repealing the market-based data collection requirement and market-based MS–DRG relative weight methodology does not result in a payment impact to hospitals or increase hospital burden.

8. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VII.B.2. of the preamble of this final rule, we discuss the implementation of the FCHIP demonstration, which allows

eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Budget neutrality estimates for the demonstration described in the preamble of this rule are based on the time period from August 1, 2016 through July 31, 2019 (referred to in this section as the ''initial period'' of the demonstration). Section 129 of the Consolidated Appropriations Act (Pub. L. 116–159) extends the FCHIP Demonstration by 5 years (referred to in this section as the ''extension period'' of the demonstration). The FCHIP Demonstration will resume on January 1, 2022, and CAHs participating in the demonstration project during the extension period shall begin such participation in the cost reporting year that begins on or after January 1. The initial period of the demonstration included three intervention prongs, under which specific waivers of Medicare payment rules allowed for enhanced payment: Telehealth, skilled nursing facility/nursing facility services, and ambulance services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. (We also discussed this policy in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 and 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 588894 through 58896), but did not make any changes to the policy that was adopted in FY 2017.)

We specified the payment enhancements for the demonstration initial period and selected CAHs for participation with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration program and uncertainty associated with projected Medicare utilization and costs, in the FY 2017 IPPS/LTCH PPS final rule we adopted a contingency plan (81 FR 57064 through 57065) to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 would be met. Accordingly, if analysis of claims data for the Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports, shows that increases in Medicare payments under the demonstration during the 3-year initial period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. The demonstration was projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, we will recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Because of the small scale of the demonstration, it would not be feasible to implement budget neutrality by reducing payments only to the participating CAHs. Therefore, our policy was to make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by this provider category. As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of the Act permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Under the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years, beginning in CY 2020. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58895), we stated that based on the currently available data, the determination of budget neutrality results was preliminary and the amount of any reduction to CAH payments that would be needed in order to recoup excess costs under the demonstration remained uncertain. Therefore, we revised the policy originally adopted in the FY 2017 IPPS/LTCH PPS final rule, to delay the implementation of any budget neutrality adjustment and stated that we would revisit this policy in rulemaking for FY 2022, when we expected to have complete data for the inital demonstration period. Based on the data and actuarial analysis described previously, we have concluded the initial period of the FCHIP demonstration (covering the time period August 1, 2016, to July 31, 2019) has satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, we are not applying a budget neutrality payment offset to payments to CAHs in FY 2022. This policy will have no impact for any national payment system for FY 2022.

9. Effects of the Policy Regarding Medicaid Enrollment of Medicare Providers and Suppliers for Purposes of Processing Claims for Cost Sharing for Services Furnished to Dually Eligible Beneficiaries

In section X.A. of the preamble of this final rule, we discuss our provision regarding Medicaid enrollment of Medicare providers and suppliers for purposes of processing claims for cost-sharing for services furnished to dually eligible beneficiaries.

Under section 1902(a)(10)(E) of the Act, States are liable for Medicare cost-sharing amounts for certain beneficiaries dually eligible for Medicare and Medicaid, including those in the Qualified Medicare Beneficiary (QMB) program. Per section 1905(p)(3) of the Act, this cost-sharing liability includes costs incurred with respect to a QMB regardless of whether the costs incurred were for items and services covered under the Medicaid State plan. Nevertheless, some States in the past have hindered some Medicare providers from enrolling in Medicaid. As a result, these non-Medicaid-enrolled providers may not be able to submit a claim for payment of Medicare cost-sharing.

Because some States at times have not met their obligation at section 1905(p)(3) of the Act to determine Medicare cost-sharing liability, we are finalizing the addition of a new paragraph (d) to 42 CFR 455.410 to specify, in part, how States must meet this obligation. Specifically, we propose that by January 1, 2023, for purposes of determining Medicare cost-sharing liability, state Medicaid programs must accept enrollment from all Medicare-enrolled providers and suppliers (even if a provider or supplier is of a type that the State would not otherwise enroll in the state Medicaid program), if the provider otherwise meets all other Federal Medicaid enrollment requirements, including, but not limited to, all applicable provisions of 42 CFR part 455, subparts B and E.

We solicited comment on the cost and savings resulting from this policy. We received comments from close to 50 stakeholders on the new regulation as detailed in section X.A, however no comments on the impact analysis. However, we have further considered and revised this estimated impact since the proposed rule.

There are three areas where this policy would have impact; listed here and discussed in further detail later in this section.

- Updating state Medicaid systems with other provider types and cost-sharing logic.
- New providers and suppliers enrolling in state Medicaid systems.
- Reducing Medicare bad debt appeals.

We are unable to estimate the change in Medicaid program costs or on Medicare bad debt payments in this analysis because States have flexibility to choose their cost-sharing payment methodology for different provider types in their Medicaid State plan, and we do not have a clear basis for assumptions about their future choices. States can choose to pay Medicare cost-sharing at the Medicare rate, which means the State pays the amount that Medicare establishes as the cost-sharing amount. States can also choose to pay Medicare cost-sharing using the Medicaid State plan rate, which means the State takes into consideration the amount that Medicare paid when determining the amount (if any) that the State will pay to bring the provider's total payment up to the Medicaid State plan rate. Usually, the Medicaid State plan rate is lower than the Medicare rate (Medicare paid amount), resulting in no additional Medicare cost-sharing payment to the provider from the State. However, if the Medicaid State plan rate is higher than the Medicare rate (Medicare paid amount), the State would then pay the difference between the Medicare paid amount and the Medicaid State plan rate. States can also choose to apply a lesser-of policy, in which States pay the lesser of the cost-sharing based on the Medicare rate or the Medicaid State plan rate. Lastly, States can pay at a negotiated rate.

Historically, most States elect a lesser-of policy for state payment of cost-sharing for hospital claims, meaning that they pay very little, if any, Medicare cost-sharing. For example, 43 States used the lesser-of policy for cost-sharing for Medicare inpatient hospital claims in 2018. Therefore, it seems plausible that these States would choose to elect lesser-of payment policies for any newly enrolled providers, generally limiting new cost-sharing liability to zero. However, because States have the flexibly to set their cost-sharing methodology for newly enrolled provider types, we have not estimated costs based on those future elections. However, by properly processing claims for Medicare cost-sharing it ensures Medicare is not inappropriately paying bad debt on any cost-sharing liability the State should have paid through its Medicaid State plan elections.

a. Updating State Medicaid Systems With Other Provider Types and Cost-Sharing Logic

While some States in the past have inhibited enrollment of certain types of providers or suppliers that are not explicitly included in their Medicaid State plan, we have no sound basis upon which to estimate how many States will need to make systems changes to implement the policy. We estimate a one-time burden for any state or territory Medicaid program that needs to make systems changes to comply with the provider enrollment requirement as indicated in section X.A of the preamble of this final rule. We estimate that it would take a maximum of 6 months of work (approximately 960 hours) by a computer programmer working at a Bureau of Labor Statistics (BLS) mean hourly rate of $44.53 per hour to make the necessary systems changes. We project a cost per State of approximately $42,749 (960 * $44.53 = $42,749). States are likely eligible for 90/10 Federal medical assistance percentage (FMAP) for the State Medicaid Management Information System (MMIS) as set forth in 1903(a)(3)(A) of the Act.

We estimate a 6-month implementation period for these system updates. In this final rule, there will be 17 months between when we publish the final rule in August 2021, and the January 1, 2023 applicability date. The purpose of the 17-month window is to give organizations flexibility to find a 6-month period to perform updates as indicated in section X.A. of the preamble of this final rule. States have the ability to choose, in consultation with CMS, when in the 17-month implementation period they want to make this change. Therefore, as noted previously, the total cost impact per State of $42,749 will occur over 6 months within this 17-month period.

b. New Providers and Suppliers Enrolling in State Medicaid Systems

We are uncertain how many providers and suppliers will seek to newly enroll in Medicaid as a result of this policy. We estimate enrollment will take an average of three hours for a provider office manager, at a BLS mean hourly rate of $28.91 per hour, to complete and would cost $86.73 for each provider (3 hours * $28.91/hr). Therefore, for every 100 providers and suppliers that apply to enroll in Medicaid, we estimate a cost of $8,673. We assume that it will take States a similar amount of time to review and process these enrollment applications. Therefore, for every 100 providers and suppliers for which a State will need to process enrollment applications, we estimate the total cost per State is $8,673.

c. Reducing Medicare Bad Debt Appeals

This final rule will not affect existing bad debt appeals. However, we believe the final rule may reduce the number of future bad debt appeals by ensuring certain Medicare-enrolled providers and suppliers can enroll with state Medicaid programs, receive Medicaid Remittance Advice (RA), and claim Medicare bad debt. In eliminating these appeals, the provision will eliminate the cost for providers and suppliers to pursue such appeals and subsequent litigation, as well as the costs for CMS to defend them. Therefore, we estimate provider and Medicare cost savings from avoiding future Medicare bad debt appeals. As noted previously, we did not estimate a reduction in Medicare bad debt payments that would result from an increase in State payment of Medicare cost-sharing because States have flexibility to choose their cost-sharing payment methodology for different provider types in their Medicaid State plan, and we do not have a clear basis for assumptions about their future choices.

While we cannot predict the outcome of future appeals and litigation, the February 2021 decision in the *Select Specialty Hospital—Denver* v. *Azar* case, which included claims from 77 providers in 26 states from 2005 to 2010, helps us better understand the potential costs avoided by finalizing this provision.

Medicare Hospital Insurance Trust Fund Payments. After an adverse decision for CMS in that case, the Federal government ultimately paid the plaintiffs a total of $23,649,492, which included the principal amount of $18,656,588 for the payment of bad debt claims that had been denied, plus associated interest of $4,992,904. This provision helps ensure that the amount paid for bad debt accurately reflects State liability; it would also eliminate costs associated with interest, should future cases be decided similarly to *Select Specialty Hospital—Denver* v. *Azar.*

Litigation costs. In the case, the plaintiffs sought $1,174,000 in total costs of attorneys' fees and costs incurred to litigate denied Medicare bad debt claims dating from 2005 to 2010 through the Medicare Provider Reimbursement Review Board (PRRB) and in Federal District Court. The court denied this request, so these costs were borne by the providers. Their true litigation costs might have been higher since there were subsequent proceedings in the case not reflected in the fee request.

The Federal government also bears significant costs to process and defend these appeals and subsequent litigation: The Medicare Administrative Contractor (MAC) and the Federal Specialized Service prepare the documentation to present at the PRRB; the PRRB holds a hearing and issues a decision; the CMS Attorney Advisor disseminates the PRRB decision to the appropriate parties, such as the Federal Specialized Service and CMS payment policy staff, for input on the PRRB decision and then issues a final Administrator's decision on the case, if appropriate; the Office of General Council defends the case in court, prepares and files briefs and motions, which may also involve components of the U.S. Department of Justice; if necessary, the Office of General Council advises CMS regarding any appropriate settlements or implementation of any adverse decisions, which the MAC then implements.

Currently, there are at least 20 open cases before the PRRB for the same issue presented in the *Select Specialty Hospital—Denver* case, involving claims with dates of service from 2007 to 2020. We estimate the provider bad debt reimbursement in controversy across these 20 open cases to be $17,248,242. Of these 20 open cases, nine cases are under remand from the Federal District Court with a calculated potential interest amount of $2,740,794.

Because we are finalizing this proposal, it is likely that appeals on this issue, and their associated costs for Medicare providers and for the Federal government described previously, will not continue into the future.

In sum, we note that the estimated costs saved by providers, CMS, and other Federal agencies in avoiding ongoing Medicare bad debt appeals likely offset the aggregate spending for providers and suppliers to enroll with state Medicaid programs, and for States to process those applications, as well as the aggregate spending for States to update the state Medicaid systems, which will likely be eligible for 90/10 FMAP, as described previously.

10. Effects of the Policy Changes to the Medicare Shared Savings Program

In section X.B. of the preamble of this final rule, we describe the changes to the Medicare Shared Savings Program (Shared Savings Program) established under section 1899 of the Act that we are adopting in this final rule. As previously communicated in the regulatory impact analysis for the preceding proposed rule, the changes are estimated to reduce program spending relative to a status quo baseline by extending the flexibility for certain ACOs to elect to ''freeze'' their participation level along the BASIC track's glide path for PY 2022. Such special flexibility—having proven popular among ACOs that chose to ''freeze'' their level of participation for PY 2021 in light of the uncertainties caused by the COVID–19 PHE, is expected to again help retain ACO participation in the program, particularly among ACOs leery of taking on downside risk, or increasing levels of downside risk, in the midst of pandemic-related uncertainty. In modeling the impacts of the changes, we used ACO performance data from the 6-month performance year from July 1, 2019, through December 31, 2019, based on CY 2019, along with preliminary data from performance year 2020 to identify ACOs that would be likely to opt for this flexibility and to estimate the potential impact on program spending. We also considered the benchmark and performance information ACOs would have available when making participation decisions for PY 2022 in the context of

participation decisions made by ACOs in similar positions entering PY 2021.

We estimate that the flexibility would prevent between 20 to 30 ACOs that would otherwise be required to transition to performance-based risk in PY 2022 from dropping out of the Shared Savings Program. Additionally, we estimate that between 60 to 80 ACOs that would otherwise attempt the transition to performance-based risk would, out of caution, opt to stay in a one-sided model in PY 2022 (that is BASIC track Level A or B) despite the opportunity to graduate to a higher level of potential reward (under BASIC track Levels A and B, ACOs share at most 40 percent of savings, whereas BASIC track Levels C, D, and E allow for greater upside potential with a maximum sharing rate of 50 percent). The net effect of offering this flexibility is estimated to be a $90 million reduction in Federal spending, with the reduction ranging from $50 to $140 million. The estimated impact is roughly evenly split between net savings generated by ACOs that would otherwise have terminated their participation in the program absent the flexibility and reduced shared savings payouts to ACOs that elect to remain at the lower sharing rates in Levels A or B of the BASIC track despite the fact they would have ultimately earned—as a group—more shared savings had they transitioned to a risk arrangement in Level C, D, or E of the BASIC track. Although we have estimated the impact of this policy over the single performance year for which it would expand certain ACOs' participation options, it is possible there could be secondary impacts over a longer time period. However, we do not believe the longer run potential effects are readily quantifiable. On one hand, the final policy could allow certain ACOs to delay making more aggressive care delivery changes if they expect CMS is likely to continue to offer risk-free participation in the program in future rulemaking, as has been the case for two successive rules (the May 8, 2020 COVID–19 interim final rule with comment period and this FY 2022 IPPS/LTCH PPS final rule). On the other hand, the final policy could give other ACOs additional time to grow in confidence in their ability to manage the transition to risk, while at the same time finding stability in their operations after the disruption from the COVID–19 PHE. ACOs in the latter category may then find longer-term success (including driving lower net spending for the program) that might have otherwise been curtailed had the ACO been forced to transition to performance-based risk for PY 2022. These two scenarios illustrate potential countervailing longer run impacts from the ''freeze'' for PY 2022, and while we have not attempted to estimate a net impact across the mix of such possible scenarios for ACOs impacted by this policy, we assert that offering ACOs in the BASIC track the opportunity to ''freeze'' their level of participation for PY 2022 increases the chance that the program could sustain a larger mix of participants and this outcome outweighs the risk that certain ACOs might be marginally slower to make efficiency-related changes in care delivery.

We did not receive any comments regarding the discussion of the impacts of this policy in the proposed rule. As discussed in section X.B. of the preamble of this final rule, we are finalizing the proposed policy without modification. Furthermore, our projection of the impact of this change has not changed from what was previously communicated in the proposed rule.

I. Effects of Changes in the Capital IPPS

1. General Considerations

As discussed, in section III.A of the Addendum to this final rule, we used claims from the March 2020 update of the FY 2019 MedPAR file and provider data from the March 2020 update of the Provider Specific File (PSF) for purposes of determining the capital Federal rate for FY 2022. Consistent with these policies, for the impact analysis presented in this section, we used data from the March 2020 update of the FY 2019 MedPAR file and the March 2020 update of the PSF that was used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2021 update of the hospital cost report data (FYs 2017 and 2018) to categorize hospitals. Our analysis has several qualifications and uses the best data available, as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we drew upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2020 update of the FY 2019 MedPAR file, we simulated payments under the capital IPPS for FY 2021 and the payments for FY 2022 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2022 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this final rule, the update to the capital Federal rate is 0.80 percent for FY 2022.
- In addition to the FY 2022 update factor, the FY 2022 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 1.0004, a budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases policy of 0.9974, and an outlier adjustment factor of 0.9471.

2. Results

We used the payment simulation model previously described in section I.I. of Appendix A of this final rule to estimate the potential impact of the changes for FY 2022 on total capital payments per case, using a universe of 3,195 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2020 update of the FY 2019 MedPAR file, the March 2020 update to the PSF, and the cost report data for FYs 2017 and 2018 from the March 2021 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2021 and estimated total payments per case for FY 2022 based on the FY 2022 payment policies. Column 2 shows estimates of payments per case under our model for FY 2021. Column 3 shows estimates of payments per case under our model for FY 2022. Column 4 shows the total percentage change in payments from FY 2021 to FY 2022. The change represented in Column 4 includes the 0.80 percent update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2022 are expected to increase as compared to capital payments per case in FY 2021. This expected increase overall is primarily due to the 0.80 percent update to the capital Federal rate for FY 2022 and the reinstatement of the imputed floor in a non-budget neutral manner. The increase in capital payments due to these changes was partially offset by an estimated decrease in capital DSH payments due to the estimated increase in the number of hospitals that reclassify from urban to rural under § 412.103. We approximate that there are 82 hospitals classified as urban (for payment purposes) and receiving capital DSH payments in FY 2021, that will be classified as rural (for payment purposes) and will not receive capital DSH payments in FY 2022. Under § 412.320, in order to receive capital DSH payments a hospital must be located in an urban area for payment purposes and have 100 or more beds, and paragraph (a)(1)(iii) specifies that the geographic classification of an urban hospital that is reclassified as rural as set forth in § 412.103 is rural. In general, regional variations in estimated capital payments per case in FY 2022 as compared to capital payments per case in FY 2021 are

primarily due to the changes in GAFs, and are generally consistent with the projected changes in payments due to changes in the wage index (and policies affecting the wage index), as shown in Table I in section I.G. of this Appendix A.

The net impact of these changes is an estimated 0.9 percent increase in capital payments per case from FY 2021 to FY 2022 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in both urban and rural classifications would experience an increase in capital IPPS payments per case in FY 2022 as compared to FY 2021. Capital IPPS payments per case will increase by an estimated 0.9 percent for hospitals in urban areas while payments to hospitals in rural areas will increase by 1.5 percent in FY 2021 to FY 2022.

The comparisons by region show that the estimated increases in capital payments per case from FY 2021 to FY 2022 for all urban areas ranging from a 0.2 percent increase for the West South Central region to a 1.5 percent increase for the New England and South Atlantic regions. We also estimate that all rural regions are expected to experience an increase in capital payments per case from FY 2021 to FY 2022, ranging from 0.8 percent for the Pacific rural region to 2.3 percent for the West South Central rural region. These regional differences are primarily due to the changes in the GAFs and estimated changes in outlier and DSH payments.

All Hospital types of ownerships (Voluntary, Proprietary, and Government) are expected to experience an increase in capital payments per case from FY 2021 to FY 2022. Government hospitals are expected to experience an increase in capital IPPS payments of 0.4 percent, and the projected increase in capital payments for proprietary and voluntary hospitals is estimated to be 1.0 percent and 0.9 percent, respectively.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2022. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this final rule for FY 2022, we show the average capital payments per case for reclassified hospitals for FY 2022. Urban reclassified hospitals are expected to experience an increase in capital payments of 0.3 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 1.3 percent. The lower expected increase in payments for urban reclassified hospitals compared to urban nonreclassified hospitals is primarily due to estimated decreases in capital DSH payments to urban reclassified hospitals caused by the increase in the number of hospitals that reclassify from urban to rural under § 412.103. Section 401 Reclassified Hospitals (that is, hospitals that reclassify from urban to rural under § 412.103) are expected to experience a decrease in capital payments of 0.1 percent. The estimated percentage increase for both rural reclassified and nonreclassified hospitals is 1.4 percent.

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TABLE III.--COMPARISON OF TOTAL PAYMENTS PER CASE [FY 2021 PAYMENTS COMPARED TO FY 2022 PAYMENTS]				
	Number of Hospitals	Average FY 2021 Payments/ Case	Average FY 2022 Payments/ Case	Change
All hospitals	3,195	981	990	0.9
By Geographic Location:				
Urban Hospitals	2,459	1,014	1,023	0.9
Rural areas	736	673	683	1.5
Bed Size (Urban)				
0-99 beds	634	803	813	1.2
100-199 beds	754	860	871	1.3
200-299 beds	427	939	949	1.1
300-499 beds	421	1,020	1,029	0.9
500 or more beds	223	1,215	1,221	0.5
Bed Size (Rural)				
0-49 beds	311	568	577	1.6
50-99 beds	253	626	634	1.3
100-149 beds	94	666	675	1.4
150-199 beds	39	737	750	1.8
200 or more beds	39	797	810	1.6
By Region:				
Urban by Region				
New England	112	1,104	1,121	1.5
Middle Atlantic	304	1,129	1,134	0.4
South Atlantic	402	889	902	1.5
East North Central	381	966	975	0.9
East South Central	144	863	869	0.7
West North Central	160	989	994	0.5
West South Central	364	927	929	0.2
Mountain	172	1,023	1,032	0.9
Pacific	370	1,304	1,314	0.8
Rural by Region				
New England	19	937	953	1.7
Middle Atlantic	50	651	662	1.7
South Atlantic	114	623	637	2.2
East North Central	113	681	687	0.9
East South Central	144	630	636	1.0
West North Central	89	701	709	1.1
West South Central	135	602	616	2.3
Mountain	48	765	773	1.0
Pacific	24	869	876	0.8
By Payment Classification:				
Urban hospitals	1,983	982	995	1.3
Rural areas	1,212	980	981	0.1
Teaching Status:				
Non-teaching	2,031	817	828	1.3
Fewer than 100 Residents	907	941	949	0.9

TABLE III.--COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2021 PAYMENTS COMPARED TO FY 2022 PAYMENTS]

	Number of Hospitals	Average FY 2021 Payments/ Case	Average FY 2022 Payments/ Case	Change
100 or more Residents	257	1,358	1,365	0.5
Urban DSH:				
Non-DSH	502	904	915	1.2
100 or more beds	1,227	1,008	1,022	1.4
Less than 100 beds	348	728	737	1.2
Rural DSH:				
Sole Community (SCH/EACH)	265	751	750	-0.1
Referral Center (RRC/EACH)	608	1,030	1,031	0.1
100 or more beds	30	895	875	-2.2
Less than 100 beds	215	559	567	1.4
Urban teaching and DSH:				
Both teaching and DSH	679	1,075	1,090	1.4
Teaching and no DSH	74	981	993	1.2
No teaching and DSH	896	866	878	1.4
No teaching and no DSH	334	859	870	1.3
Special Hospital Types:				
Non special status hospitals	152	781	776	-0.6
RRC/EACH	523	1,061	1,063	0.2
SCH/EACH	305	758	758	0.0
Medicare-dependent hospitals (MDH)	153	610	616	1.0
SCH, RRC and EACH	154	807	815	1.0
MDH, RRC and EACH	27	687	694	1.0
Type of Ownership:				
Voluntary	1,881	993	1,002	0.9
Proprietary	828	896	905	1.0
Government	486	1,031	1,035	0.4
Medicare Utilization as a Percent of Inpatient Days:				
0-25	643	1,119	1,125	0.5
25-50	2,110	972	981	0.9
50-65	367	797	804	0.9
Over 65	50	586	596	1.7
2022 Reclassifications by the Medicare Classification Review Board:				
All Reclassified Hospitals	934	987	993	0.6
All Nonreclassified Hospitals	2,261	977	988	1.1
Urban Hospitals Reclassified	749	1,039	1,042	0.3
Urban Nonreclassified Hospitals	1,723	995	1,008	1.3
Rural Hospitals Reclassified Full Year	300	695	705	1.4
Rural Nonreclassified Hospitals Full Year	423	641	650	1.4
All Section 401 Reclassified Hospitals	532	1,073	1,072	-0.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	662	672	1.5

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J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VIII. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2022. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify the policies for FY 2022, and present rationales for our provisions as well as alternatives that were considered. In this section of Appendix A to this final rule, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated

fiscal impact on the Medicare budget and on LTCHs.

There are 363 LTCHs included in this impact analysis. We note that, although there were 373 LTCHs with cases in the FY 2019 MedPAR files, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2022 MS–LTC–DRG relative weights (discussed in section VIII.B.3.c. of the preamble of this final rule. Moreover, in the claims data used for this final rule, 3 of these 363 LTCHs only have claims for site neutral payment rate cases and, therefore, do not affect our impact analysis for LTCH PPS standard Federal payment rate cases.)

In the impact analysis, we used the payment rate, factors, and policies presented in this final rule, the 1.9 percent annual update to the LTCH PPS standard Federal payment rate, the update to the MS–LTC–DRG classifications and relative weights, the update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2022.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2). In addition, there are two separate high cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019. For FY 2021 and FY 2022, we expected no site neutral payment rate cases would still be eligible for the transitional payment method since it only applies to those site neutral payment rate cases whose discharges occur during a LTCH's cost reporting period that begins before October 1, 2019. Site neutral payment rate cases whose discharges from an LTCH occur during the LTCH's cost reporting period that begins on or after October 1, 2019 are paid the site neutral payment rate amount determined under § 412.522(c)(1). Therefore, for purposes of this impact analysis, to estimate total LTCH PPS payments for site neutral payment rate cases in FYs 2021 and 2022 the site neutral payment rate amount was applied in full.

Based on the best available data for the 363 LTCHs in our database that were considered in the analyses used for this final rule, we estimate that overall LTCH PPS payments in FY 2022 will increase by approximately 1.1 percent (or approximately $42 million) based on the rates and factors presented in section VIII. of the preamble and section V. of the Addendum to this final rule.

Based on the FY 2019 LTCH cases that were used for the analysis in this final rule, approximately 25 percent of those cases were classified as site neutral payment rate cases (that is, 25 percent of LTCH cases did not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2022 will not change significantly from the most recent historical data. Taking into account updates to the IPPS rates and other changes that will apply to the site neutral payment rate cases in FY 2022, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will increase by approximately 3 percent (or approximately $11 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the updates to the IPPS rates used in calculating the IPPS comparable per diem amount, as well as an estimated increase in costs for these cases determined using the charge and CCR adjustment factors described in section V.D.3.b. of the Addendum to this final rule. We note, we estimate payments to site neutral payment rate cases in FY 2022 represent approximately 10 percent of estimated aggregate FY 2022 LTCH PPS payments.

Based on the FY 2019 LTCH cases that were used for the analysis in this final rule, approximately 75 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2022, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2022 will increase approximately 0.9 percent (or approximately $31 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2022 is primarily due to the 1.9 percent annual update to the LTCH PPS standard Federal payment rate for FY 2022 and the projected 0.8 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, which is discussed later in this section.

Based on the 363 LTCHs that were represented in the FY 2019 LTCH cases that were used for the analyses in this final rule presented in this Appendix, we estimate that aggregate FY 2021 LTCH PPS payments will be approximately $3.771 billion, as compared to estimated aggregate FY 2022 LTCH PPS payments of approximately $3.813 billion, resulting in an estimated overall increase in LTCH PPS payments of approximately $42 million. We note that the estimated $42 million increase in LTCH PPS payments in FY 2022 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the policies in this final rule.

The LTCH PPS standard Federal payment rate for FY 2021 is $43,755.34. For FY 2022, we are establishing an LTCH PPS standard Federal payment rate of $ 44,713.67 which reflects the 1.9 percent annual update to the LTCH PPS standard Federal payment rate and the budget neutrality factor for the updates to the area wage level adjustment of 1.002848 (discussed in section V.B.6. of the Addendum to this final rule). For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $43,836.08. This LTCH PPS standard Federal payment rate reflects the updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP.

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the annual update of 1.9 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 1.8 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022, on average, for all LTCHs (Column 6). The estimated increase of 1.8 percent shown in Column 6 of Table IV also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. For most hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases also rounds to approximately 1.8 percent.

For FY 2022, we are updating the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2018 which is the same data used for the FY 2022 IPPS wage index). In addition, we are establishing a labor-related share of 67.9 percent for FY 2022, based on the most recent available data (IGI's second quarter 2021 forecast) on the relative importance of the labor-related share of operating and capital costs of the 2017-based LTCH market basket. We also applying an area wage level budget neutrality factor of 1.002848 to ensure that the changes to the area wage level adjustment will not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

For LTCH PPS standard Federal payment rate cases, we currently estimate high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will decrease from FY 2021 to FY 2022. Based on the FY 2019 LTCH cases that were used for the analyses in this final rule, we estimate that the FY 2021 high cost outlier threshold of $27,195 (as established in the FY 2021 IPPS/LTCH PPS final rule) will result in estimated high cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2021 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 8.8 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2021. Combined with our estimate that FY 2022 high cost outlier

payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2022, this will result in an estimated decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments of approximately 0.83 percent between FY 2021 and FY 2022. We note that, in calculating these estimated high cost outlier payments, we inflated charges reported on the FY 2019 claims by the charge inflation factor in section V.D.3.b. of the Addendum to this final rule. We also note that, in calculating these estimated high cost outlier payments, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our methodology described in section V.D.3.b. of the Addendum to this final rule.

Table IV shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2022 by comparing estimated FY 2021 LTCH PPS payments to estimated FY 2022 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

As we discuss in detail throughout this final rule, based on the best available data, we believe that the provisions of this final rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

Comment: Multiple commenters expressed concerns about the application of the site neutral payment rate once the PHE waivers are ended. Several of these commenters stated their belief that cases paid at the site neutral payment rate will continue to be underpaid as those cases, according to commenters, have on average higher levels of clinical complexity and costs that significantly exceed IPPS-level payment and that the lower payment of site neutral cases relative to the LTCH PPS standard Federal payment rate has negatively impacted LTCHs as a provider type. Some of these commenters acknowledged that CMS is unable to change this policy but request that CMS take into consideration the costs of site neutral payment rate cases when proposing any future changes to the LTCH PPS.

A commenter expressed concern that our impact analysis is done based on LTCHs as a class of providers and not on a hospital-by-hospital basis.

Response: We acknowledge commenters' concerns about the costs of treating site neutral cases, however, as noted by some commenters and discussed previously, the site neutral payment rate is a statutory requirement. We will consider the costs of site neutral payment rate cases as appropriate in future rulemaking. For readers interested in the provider-level data used for this impact analysis, we refer them to the FY 2022 LTCH PPS Final Rule Impact File which can be found on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/LTCHPPS-Historical-Impact-Files*.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 1.2 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This estimated impact is based on the FY 2019 data for the 19 rural LTCHs (out of 360 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable high cost outlier (HCO) payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent.

As discussed in section I.J.2. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2022 of approximately $42 million. This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $31 million and the projected increase in payments to site neutral payment rate cases of approximately $11 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section V.D. of the Addendum to this final rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this final rule to project estimated FY 2022 LTCH PPS payments (that is, FY 2019 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this final rule on different categories of LTCHs for FY 2022, it is necessary to estimate payments per discharge for FY 2021 using the rates, factors, and the policies established in the FY 2021 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2022 using the rates, factors, and the policies in this FY 2022 IPPS/LTCH PPS final rule (as discussed in section VIII. of the preamble of this final rule and section V. of the Addendum to this final

rule). As discussed elsewhere in this final rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2021 and final FY 2022 payments on a case-by-case basis using historical LTCH claims from the FY 2019 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2019 MedPAR files. For modeling FY 2021 LTCH PPS payments, we used the FY 2021 standard Federal payment rate of $43,755.34 (or $42,899.90 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the FY 2022 LTCH PPS standard Federal payment rate, we used the final FY 2022 standard Federal payment rate of $44,713.67 (or $43,836.08 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2021 LTCH PPS payments, we used the current FY 2021 labor-related share (68.1 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2021 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2021 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,195 (as reflected in the FY 2021 IPPS/LTCH PPS final rule), and the FY 2021 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2021 nonlabor-related share (31.9 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2022 LTCH PPS payments, we used the FY 2022 LTCH PPS labor-related share (67.9 percent), the FY 2022 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the internet on the CMS website), the FY 2022 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $33,015 (as discussed in section V.D.3. of the Addendum to this final rule), and the FY 2022 COLA factors (shown in the table in section V.C. of the Addendum to this final rule) to adjust the FY 2022 nonlabor-related share (32.1 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we inflated charges reported on the FY 2019 claims by the charge inflation factors in section V.D.3.b. of the Addendum to this final rule. We also note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our methodology described in section V.D.3.b. of the Addendum to this final rule.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2021 to FY 2022 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2021 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated FY 2022 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2021 to FY 2022 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 for changes to the area wage level adjustment (that is, the updated hospital wage data and labor-related share) and the application of the corresponding budget neutrality factor (as discussed in section V.B.6. of the Addendum to this final rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 (Column 4) to FY 2022 (Column 5) for all changes.

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TABLE IV: IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2022 (ESTIMATED FY 2021 PAYMENTS COMPARED TO ESTIMATED FY 2022 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2021 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2022 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	360	68,764	49,651	50,107	1.8	0.0	0.9
BY LOCATION:							
RURAL	19	2,819	39,596	40,081	1.9	0.1	1.2
URBAN	341	65,945	50,081	50,535	1.8	0.0	0.9
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	10	1,788	46,792	47,023	1.8	-0.2	0.5
OCT. 1983 - SEPT. 1993	40	8,883	55,330	55,849	1.8	0.1	0.9
OCT. 1993 - SEPT. 2002	145	28,209	48,599	49,045	1.8	0.0	0.9
AFTER OCTOBER 2002	165	29,884	49,127	49,587	1.8	0.0	0.9
BY OWNERSHIP TYPE:							
VOLUNTARY	60	8,517	52,453	52,781	1.8	0.0	0.6
PROPRIETARY	290	59,088	49,024	49,494	1.8	0.0	1.0
GOVERNMENT	10	1,159	61,027	61,699	1.8	0.6	1.1
BY REGION:							
NEW ENGLAND	10	2,374	44,563	44,782	1.8	-0.6	0.5
MIDDLE ATLANTIC	23	5,310	57,600	57,809	1.8	-0.7	0.4
SOUTH ATLANTIC	62	13,107	48,965	49,549	1.8	0.3	1.2
EAST NORTH CENTRAL	55	10,260	48,616	49,006	1.9	-0.1	0.8
EAST SOUTH CENTRAL	31	5,784	44,635	45,042	1.9	0.0	0.9
WEST NORTH CENTRAL	22	4,152	47,110	47,508	1.9	0.3	0.8
WEST SOUTH CENTRAL	105	17,198	44,596	44,937	1.9	-0.3	0.8
MOUNTAIN	29	3,371	50,753	51,520	1.8	0.4	1.5
PACIFIC	23	7,208	65,226	66,003	1.7	0.2	1.2
BY BED SIZE:							
BEDS: 0-24	22	2,243	47,639	47,939	1.9	0.0	0.6
BEDS: 25-49	166	23,651	46,484	46,952	1.9	0.0	1.0

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d. Results

Based on the FY 2019 LTCH cases (from 363 LTCHs) that were used for the analyses in this final rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2021 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2022 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
BEDS: 50-74	97	19,086	50,069	50,534	1.8	0.0	0.9
BEDS: 75-124	48	13,852	53,853	54,372	1.8	0.0	1.0
BEDS: 125-199	19	5,977	51,675	51,992	1.8	-0.3	0.6
BEDS: 200+	8	3,955	49,938	50,355	1.8	-0.1	0.8

[1] Estimated FY 2022 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this final rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 for the annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 for changes due to the changes to the area wage level adjustment under § 412.525(c) (that is, updated hospital wage data and the labor related share).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 (shown in Column 4) to FY 2022 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this final rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes due to the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

cases are projected to increase 0.9 percent, on average, for all LTCHs from FY 2021 to FY 2022 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. This estimated 0.9 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2022 LTCH PPS payments (using the payment rates and factors discussed in this final rule) to estimated FY 2021 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are updating the LTCH PPS standard Federal payment rate for FY 2022 by 1.9 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. Consistent with § 412.523(d)(4), we also are applying a budget neutrality factor for changes to the area wage level adjustment of 1.002848 (discussed in section V.B.6. of the Addendum to this final rule), based on the best available data at this time, to ensure that any changes to the area wage level adjustment will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the 1.9 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 1.8 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2021 to FY 2022. We note our estimate of the changes in payments due to the update to the LTCH PPS standard Federal payment rate also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 for all hospitals is 0.9 percent. The projected increase for urban hospitals is 0.9 percent for urban hospitals, while the projected increase for rural hospitals is 1.2 percent.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the best available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 41 percent and 43 percent, respectively) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002 and after October 2002. These LTCHs are expected to both experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 of 0.9 percent. LTCHs that began participating in the Medicare program between October 1983 and September 1993 are also projected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 of 0.9 percent, as shown in Table IV. Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase of 0.5 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the best available data, approximately 17 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, voluntary and proprietary LTCHs are each expected to experience an increase of 0.6 percent and 1.0 percent in payments to LTCH PPS standard Federal payment rate cases, respectively. Government owned and operated LTCHs, meanwhile, are expected to experience a 1.1 percent increase in payments to LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2022 are projected to increase across all census regions. LTCHs located in the Mountain region are projected to experience the largest increase at 1.5 percent. The remaining regions are projected to experience an increase in payments in the range of 0.4 to 1.2 percent. These regional variations are primarily due to the changes to the area wage adjustment.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 0–24 beds and 125–199 beds will experience the lowest increase in payments for LTCH PPS standard Federal payment rate cases, 0.6 percent. LTCHs with 25–49 beds and 75–124 beds are projected to experience the largest increase in payments of 1.0 percent. LTCHs with 50–74 beds and greater than 200 beds are projected to experience an increase in payments of 0.9 percent and 0.8 percent, respectively.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2022 relative to FY 2021 of approximately $31 million (or approximately 0.9 percent) for the 363 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2022 relative to FY 2021 of approximately $11 million (or approximately 3 percent) for the 363 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2022 represent approximately 10 percent of total estimated FY 2022 LTCH PPS payments.) Therefore, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2022 relative to FY 2021 of approximately $42 million (or approximately 1.1 percent) for the 363 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this final rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section IX.C. of the preamble of this final rule, we discuss our current requirements and finalized proposals for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2023 payment determination and subsequent years.

In this final rule, we are finalizing: (1) Adopting the Maternal Morbidity structural measure beginning with a shortened reporting period from October 1 through December 31, 2021 (affecting the FY 2023 payment determination), followed by annual reporting periods (affecting the FY 2024 payment determination and subsequent years); (2) adopting the Hybrid HWM measure beginning with a 1-year voluntary reporting period beginning July 1, 2022 through June 30, 2023, before requiring mandatory reporting of the measure for the

reporting period that would run from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years; (3) adopting the COVID–19 Vaccination Coverage among HCP measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021 affecting the FY 2023 payment determination followed by quarterly reporting deadlines affecting the FY 2024 payment determination and subsequent years; (4) adopting two medication-related adverse event eCQMs (Hospital Harm-Severe Hypoglycemia eCQM and Hospital Harm-Severe Hyperglycemia eCQM) beginning with the CY 2023 reporting period/FY 2025 payment determination; (5) removing the Discharged on Statin Medication eCQM (STK–06) beginning with the FY 2026 payment determination; (6) removing the Exclusive Breast Milk Feeding (PC–05) measure beginning with the FY 2026 payment determination; (7) removing the Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) measure beginning with the FY 2026 payment determination; (8) revising regulations at 42 CFR 412.140(a)(2) by replacing the term ''QualityNet Administrator'' with the term ''QualityNet security official'' and 42 CFR 412.140(e)(2)(iii) by replacing the term ''QualityNet system administrator'' with the term ''QualityNet security official''; (9) revising regulations at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i) to remove references to ''QualityNet.org'' and replace with ''QualityNet website''; (10) requiring the 2015 Edition Cures Update of CEHRT for eCQMs and hybrid measures beginning with the FY 2025 payment determination; and (11) extending the effects of educational reviews for fourth quarter data such that if an error is identified during the education review process for fourth quarter data, we will use the corrected quarterly score to compute the final confidence interval used for payment determination beginning with validations affecting the FY 2024 payment determination. We are not finalizing our proposal to remove the Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK–03) or the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) measure.

As shown in summary table in section XII.B.7.k. of the preamble of this final rule, we estimate a total information collection burden increase for 3,300 IPPS hospitals of 2,475 hours at a cost of $101,475 annually associated with our finalized policies and updated burden estimates across a 4-year period from the CY 2022 reporting period/FY 2024 payment determination through the CY 2025 reporting period/FY 2027 payment determination, compared to our currently approved information collection burden estimates. Note that for the CY 2022 reporting period/FY 2024 payment determination, the total burden increase is only 1,375 hours at a cost of $56,375 due to reporting of the Hybrid HWR measure being only for two quarters versus four quarters for the CY 2023 reporting period/FY 2025 payment determination and subsequent years. We refer readers to section XII.B.7. of the preamble of this final rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital IQR Program.

As described in sections IX.C.9.e. and IX.C.9.f. of the preamble of this final rule, as proposed, we are finalizing an update to certification requirements requiring the use of the 2015 Edition Cures Update for eCQMs and hybrid measures beginning with the FY 2025 payment determination. We expect this policy to have no impact on information collection burden for the Hospital IQR Program because this policy does not require hospitals to submit new data to CMS. With respect to any costs unrelated to data submission, although this finalized policy will require some investment in systems updates, the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs) previously finalized a requirement that hospitals use the 2015 Edition Cures Update for eCQMs (85 FR 84818 through 84825). Because all hospitals participating in the Hospital IQR Program are subsection (d) hospitals that also participate in the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), we do not anticipate any additional costs as a result of this finalized policy. This is because the burden and costs involved in updating to the 2015 Edition Cures Update is the same regardless of whether the technology is used for eCQMs or hybrid measures. Hybrid measure data are derived from both claims and clinical EHR data, via submission of QRDA I files, and we already collect and utilize claims data and QRDA I file data for other measures in the Hospital IQR Program measure set. In other words, what hospitals need to do is not measure-dependent. Therefore, we believe that the Medicare Promoting Interoperability Program has already addressed the additional costs unrelated to data submission through their previously finalized requirements.

We also note that in sections IX.C.5. and IX.C.6 of the preamble of this final rule, we are finalizing our proposals to adopt two new eCQMs and remove three eCQMs. We are not finalizing our proposal to remove Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK–03); however, this retention will not change impacts to hospitals. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQM measures, while there is no change in information collection burden related to those finalized provisions, we believe that costs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining Program measures in hospitals' EHR systems for all of the eCQMs available for use in the Hospital IQR Program (83 FR 41771).

In section IX.C.5.c. of the preamble of this final rule, as proposed, we are finalizing our proposal to adopt a COVID–19 Vaccination Coverage among HCP measure beginning with a reporting period from October 1 to December 31, 2021 affecting the CY 2021 reporting period/FY 2023 payment determination followed by quarterly reporting beginning with the FY 2024 payment determination and subsequent years.[1394] Regarding public reporting of this measure, based on public comment, we are finalizing a modification to our proposal. Under this modification, we will not finalize our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then publicly report the measure using four rolling quarters of data. Instead, we will only publicly report the most recent quarter of data. However, this will not change the impacts to hospitals as we are finalizing the data submission requirements as proposed. Hospitals would submit data through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[1395]

Although the burden associated with the COVID–19 Vaccination Coverage among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information are included in this section. We estimate that it will take each IPPS subsection (d) hospital, on average, 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe an Administrative Assistant[1396] would spend between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. For the shortened CY 2021 reporting period, 3 months are required. For the CY 2021 reporting period/FY 2023 payment determination, IPPS subsection (d) hospitals would incur an additional burden between 2.25 hours (0.75 hours × 3 months) and 3.75 hours (1.25 hours × 3 months) per hospital. For all 3,300 hospitals, the total burden would range from 7,425 hours (2.25 hours × 3,300 IPPS hospitals) and 12,375 hours (3.75 hours × 3,300 IPPS hospitals). Each hospital would incur an estimated cost of between $27.47 (0.75 hours × $36.62) and $45.78 (1.25 hours × $36.62) monthly and

[1394] We note that the proposed rule incorrectly read ''annual reporting periods'' however the section of the proposed rule on data submission (IX.C.5.c.) correctly described the data submission process and timelines.

[1395] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[1396] *https://www.bls.gov/oes/current/oes436013.htm* (accessed on March 30, 2021). *The adjusted hourly wage rate of $36.62/hour includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.*

between $82.40 (2.25 hours × $36.62) and $137.33 (3.75 hours × $36.62) in total over the shortened period to complete this task. Thereafter, 12 months of data are required annually (12 months × 1 hour per month) with quarterly data submission deadlines. IPPS subsection (d) hospitals would incur an additional annual burden between 9 hours (0.75 hours × 12 months) and 15 hours (1.25 hours × 12 months) per hospital and between 29,700 hours (9 hours × 3,300 IPPS hospitals) and 49,500 hours (15 hours × 3,300 IPPS hospitals) for all hospitals. Each hospital would incur an estimated cost of between $329.58 (9 hours × $36.62) and $549.30 annually (15 hours × $36.62). The estimated cost across all 3,300 IPPS hospitals would be between $271,920 ($82.40 × 3,300 IPPS hospitals) and $453,189 ($137.33 × 3,300 IPPS hospitals) for the shortened CY 2021 reporting period. The estimated cost across all 3,300 IPPS hospitals would be between $1,087,614 ($329.58 × 3,300 IPPS hospitals) and $1,812,690 ($549.30 × 3,300 IPPS hospitals) annually thereafter. We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 Vaccination Coverage among HCP measure to monitor, track, and provide transparency for the public on this important tool to combat COVID–19 outweigh the costs of reporting. We welcomed comments on the estimated time to collect data and enter it into NHSN.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of this Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years.

We did not receive any public comments regarding the estimated time to collect data and enter it into the NHSN.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.D. of the preamble of this final rule, we discuss our proposed and finalized policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section IX.D.4. of the preamble of this final rule, we are finalizing the removal of the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383/PCH–15) measure beginning with the FY 2024 program year, adopting the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2023 program year, with reporting for the FY 2023 program year from October 1 through December 31, 2021, followed by quarterly reporting periods [1397] beginning with the FY 2024 program year, and codifying existing program policies. As stated in section XII.B.7. of the preamble of this final rule, we estimated the total burden reduction associated with the removal of PCH–15 beginning with the FY 2024 program year to be 2.75 hours (0.25 hours × 11 PCHs) with a total cost reduction of $113 (2.75 hours × $41.00/hour).

In section IX.D.5. of the preamble of this final rule, we are finalizing our proposal to adopt a COVID–19 Vaccination Coverage among HCP measure beginning with a shortened reporting period from October 1 to December 31, 2021, affecting the FY 2023 program year followed by quarterly reporting [1398] beginning with the FY 2024 program year and subsequent years. PCHs will submit data through the CDC NHSN. The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[1399]

Although the burden associated with the COVID–19 Vaccination Coverage among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information are included in this section. We estimate that it would take each PCH, on average, approximately 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe it would take an Administrative Assistant [1400] between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. For the shortened CY 2021 reporting period (consisting of October 1, 2021 through December 31, 2021), 3 months would be required. For the CY 2021 reporting period/FY 2023 program year, PCHs would incur an additional burden of between 2.25 hours (0.75 hours × 3 months) and 3.75 hours (1.25 hours × 3 months) per PCH. For all 11 PCHs, the total burden would range from 24.75 hours (2.25 hours × 11 hospitals) and 41.25 hours (3.75 hours × 11 hospitals). Each PCH would incur an estimated cost of between $27.47 (0.75 hour × $36.62/hr) and $45.78 (1.25 hours × 36.62/hour) monthly and between $82.40 (2.25 hours × $36.62/hr) and $137.33 (3.75 hours × $36.62/hour) in total over the shortened period to complete this task. Thereafter, 12 months of data would be required annually. Therefore, PCHs would incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per PCH and between 99 hours (9 hours/hospital × 11 hospitals) and 165 hours (15 hours/hospital × 11 hospitals) for all PCHs. Each PCH would incur an estimated cost of between $329.58 (9 hours × $36.62/hour) and $549.30 annually (15 hours × $36.62/hour). The estimated cost across all 11 PCHs would be between $906.40 ($82.40/hospital × 11 hospitals) and $1,510.63 ($137.33/hospital × 11 hospitals) for the shortened CY 2021 reporting period. The estimated cost across all 11 PCHs would be between $3,625.38 ($329.58/hospital × 11 hospitals) and $6,042.30 ($549.30/hospital × 11 hospitals) annually thereafter. We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 Vaccination Coverage among HCP measure to monitor, track, and provide transparency for the public on this important tool to combat COVID–19 outweigh the costs of reporting. We welcomed comments on the estimated time to collect data and enter it into the NHSN.

We did not receive any public comments regarding the estimated time to collect data and enter it into the NHSN.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.E.4. of the preamble of this final rule,, we are finalizing our proposal to adopt one measure under the Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP), the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2023 LTCH QRP. We are finalizing our proposal to update a measure adopted in the FY 2020 IPPS/LTCH final rule (84 FR 42044), the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure beginning with the FY 2023 LTCH QRP. We are also finalizing our proposals to begin publicly displaying data for the quality measures Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay and the Ventilator Liberation Rate for the Post-Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) on Care Compare and PDC, and to publicly report the COVID–19 Vaccination Coverage among HCP measure on Care Compare. In addition, we are finalizing our proposal to publicly report LTCH QRP measures using fewer quarters of data than previously finalized due to an exemption we granted the LTCHs under our regulations at 42 CFR 412.560(c)(4). Finally, we sought information on two issues: CMS' future plans

[1397] We note that the proposed rule incorrectly read ''annual reporting periods'' however the section of the proposed rule on data submission (IX.D.5.c.) correctly described the data submission process and timelines.

[1398] We note that the proposed rule incorrectly read ''annual reporting periods'' however the section of the proposed rule on data submission (IX.D.5.c.) correctly described the data submission process and timelines.

[1399] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[1400] *https://www.bls.gov/oes/current/oes436013.htm* (accessed on March 30, 2021). The hourly rate of $36.62 includes an adjustment of 100 percent of the mean hourly wage to account for the cost of overhead, including fringe benefits.

to define digital quality measures (dQMs) for the LTCH QRP; the potential use of Fast Healthcare Interoperability Resources (FHIR) for dQMs within the LTCH QRP; and input on CMS continued efforts to close the health equity gap.

The CDC will account for the burden associated with the COVID–19 Vaccination Coverage among HCP measure collection under OMB control number 0920–1317 (expiration January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November 14, 1986) (NCVIA).[1401] We refer readers to section XII.B.8. of this final rule, where CMS has provided an estimate of the burden and cost to LTCHs, and note that the CDC will include it in a revised information collection request for 0920–1317.

N. Effects of Requirements Regarding the Medicare Promoting Interoperability Program

In section IX.F.3.b. of the preamble of this final rule, we are finalizing the following proposed changes for CY 2022 with eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) To maintain the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing its available bonus from five points to 10 points for the EHR reporting period in CY 2022; (2) to add a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation to the HIE objective as an optional alternative to the two existing measures, beginning with the EHR reporting period in CY 2022; (3) to require reporting on four of the existing Public Health and Clinical Data Exchange Objective measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting); (4) to add a new measure to the Protect Patient Health Information objective that requires eligible hospitals and CAHs to attest to having completed an annual assessment of the SAFER Guides, beginning with the EHR reporting period in CY 2022; (5) to remove attestation statements 2 and 3 from the Promoting Interoperability Program's prevention of information blocking requirement; and (6) to increase the minimum required score for the objectives and measures from 50 points to 60 points (out of 100 points) in order to be considered a meaningful EHR user. We are amending our regulation text as necessary to incorporate these changes.

In section IX.F.3.b. of the preamble of this final rule, we are finalizing the following proposed changes for CY 2024 with eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 180-day period in CY 2024 for new and returning participants (eligible hospitals and CAHs); and (2) to remove three eCQMs from the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2024, which is in alignment with the proposals being finalized under the Hospital IQR Program. We are not finalizing our proposal to remove Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK–03) in alignment with the Hospital IQR Program; however, this retention will not change impacts to hospitals. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQM measures, while there is no change in information collection burden related to those finalized provisions, we believe that costs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program measures in hospitals' EHR systems for all of the eCQMs available for use in the Medicare Promoting Interoperability and Hospital IQR Programs (83 FR 41771). We are amending our regulation text as necessary to incorporate these changes.

As described in section IX.F.11.4. of the preamble of this final rule, as proposed, we are finalizing an update to certification requirements requiring the use of the 2015 Edition Cures Update for eCQMs in alignment with the finalized proposal for the Hospital IQR Program, beginning with the FY 2025 payment determination. We expect this policy to have no impact on information collection burden for the Medicare Promoting Interoperability Program because this policy does not require hospitals to submit new data to CMS. Because the Medicare Promoting Interoperability Program previously finalized a requirement that hospitals use the 2015 Edition Cures Update (85 FR 84818 through 84825), we do not anticipate any additional costs as a result of this finalized policy.

For the EHR reporting period in CY 2022, the provisions summarized here are mainly extensions from or continuations of existing policies from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58966 through 58977) and finalized proposals included in the CY 2021 PFS final rule (85 FR 84825 through 84828). However, due to an update of the hospital staff professional who most likely conducts the reporting for the Medicare Promoting Interoperability Program, we have updated the Bureau of Labor Statistics wage rate. Such changes will result in an estimated total burden cost of $879,450 for CY 2022 (a net decrease of $607,893 from CY 2021). While in this final rule, we are finalizing proposals that influence programmatic policies in CY 2023 and CY 2024, we do not believe they would attribute to a rise in burden hours, meaning that both prospective years would maintain the same estimated total burden cost of $879,450. We refer readers to section XII.B. of the preamble of this final rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Medicare Promoting Interoperability Program.

We received no comments on these effects.

O. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Use of FY 2020 or FY 2019 Data in the FY 2022 IPPS and LTCH PPS Ratesetting

In the FY 2022 IPPS and LTCH PPS proposed rule (86 FR 25086 through 25090) we explained that for the IPPS and LTCH PPS ratesetting, our longstanding goal is to use the best available data. We discussed our analysis of the best available data for use in the development of the FY 2022 IPPS/LTCH PPS proposed rule given the potential impact of the PHE for COVID–19. We proposed to use FY 2019 data, such as the FY 2019 MedPAR file, for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE, primarily in that the utilization of inpatient services reflect generally markedly different utilization for certain types of services in FY 2020 than would have been expected in the absence of the PHE.

Alternatively, we considered whether we should use the FY 2020 data instead of the FY 2019 data for FY 2022 ratesetting purposes. The FY 2020 data is what CMS would ordinarily use for purposes of FY 2022 ratesetting. Public comments were largely supportive of CMS use of FY 2019 data. Most commenters agreed that, to the extent possible, CMS should use the best available data and that the PHE for COVID–19 impacted FY 2020 claims data in a way that may make it less accurate and appropriate for FY 2022 ratesetting purposes. As discussed in section II.F. of the preamble of this final rule, and following our review of public comments, we are finalizing use of the FY 2019 data for the FY 2022 IPPS and LTCH PPS ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE. For example, we are finalizing our proposal to use the FY 2019 MedPAR claims data for purposes where we ordinarily would have used the FY 2020 MedPAR claims data, such as in our analysis of changes to MS–DRG classifications (as discussed in greater detail in section II.D. of the preamble of this final rule). Similarly, we are finalizing the use of cost report data from the FY 2018 HCRIS file for purposes where we ordinarily would have used the FY 2019 HCRIS file, such as in determining the final FY 2022 IPPS MS–DRG (as discussed in greater detail in section II.D. of the preamble of this final rule) and finalized FY 2022 MS–LTC–DRG relative weights (as discussed in greater detail section VI.B. of the preamble of this final rule).

2. Market-Based MS–DRG Relative Weight Policy

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a requirement for a hospital to report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021 (85 FR 58873 through 58892); this data collection requirement was specified in

[1401] Section 321 of the NCVIA provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

42 CFR 413.20(d)(3). We also finalized the use of this data in a new market-based methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing, beginning in FY 2024. Specifically, we finalized that we would begin using the reported median payer-specific negotiated charge by MS–DRG for MA organizations in the market-based MS–DRG relative weight methodology beginning with the relative weights calculated for FY 2024.

In the FY 2022 IPPS and LTCH PPS proposed rule, we proposed to repeal the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021. We also proposed to repeal the market-based MS–DRG relative weight methodology adopted for calculating the MS–DRG relative weights effective in FY 2024, and to continue using the existing cost-based methodology for calculating the MS–DRG relative weights for FY 2024 and subsequent fiscal years.

In the FY 2022 IPPS/LTCH PPS proposed rule, we considered an alternative to our proposal to maintain the requirement that hospitals report the median payer-specific negotiated charge for MA organizations on the Medicare cost report, but delay the implementation of the market-based MS–DRG relative weight methodology from FY 2024 to a later date. Under the alternative to delay the implementation of the market-based MS–DRG relative weight methodology, we would maintain the market-based MS–DRG relative weight data collection policy, as finalized in the FY 2021 IPPS/LTCH PPS final rule, and would require that hospitals follow the steps outlined in the frequently asked questions document published on January 15, 2021 that provides examples for how hospitals would calculate the median payer specific negotiated charge so that the market-based data is comparable and consistent across different negotiation tactics used by hospitals and MA organizations.

After consideration of the public comments, as discussed in section V.L. of the preamble of this final rule, we are finalizing our proposal to repeal the requirement that hospitals report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021, as finalized in the FY 2021 IPPS/LTCH PPS final rule. We are also finalizing our proposal to repeal the market-based MS–DRG relative weight methodology adopted effective for FY 2024, as finalized in the FY 2021 IPPS/LTCH PPS final rule.

P. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $2.293 billion in FY 2022, including operating, capital, and new technology changes, as estimated for this final rule. The estimated change in operating payments is approximately $1.6 billion (discussed in section I.G. and I.H. of this Appendix). The estimated change in capital payments is approximately $0.076 billion (discussed in section I.I. of this Appendix). The estimated change in new technology add-on payments is approximately $0.65 billion as discussed in section I.H. of this Appendix. The change in new technology add-on payments reflects the net impact of new and continuing new technology add-on payments. Total may differ from the sum of the components due to rounding.

Table I. of section I.G. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the final MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals would experience a 0.9 percent increase in capital payments per case, as shown in Table III. of section I.I. of this Appendix. We project that there will be a $76 million increase in capital payments in FY 2022 compared to FY 2021.

The discussions presented in the previous pages, in combination with the remainder of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments in FY 2022. In the impact analysis, we are using the final rates, factors, and policies presented in this final rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2022. Accordingly, based on the best available data for the 363 LTCHs in our database, we estimate that overall FY 2022 LTCH PPS payments will increase approximately $42 million relative to FY 2021 primarily due to the annual update to the LTCH PPS standard Federal rate.

Q. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the proposed rule, we assumed that the total number of timely pieces of correspondence on last year's proposed rule would be the number of reviewers of the proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For those reasons, and consistent with our approach in previous rulemakings (83 FR 41777, 84 FR 42697, and 85 FR 32460), we believe that the number of past commenters would be a fair estimate of the number of reviewers of the proposed rule. We welcomed any public comments on the approach in estimating the number of entities that reviewed the proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the rule. Therefore, for the purposes of our estimate, and consistent with our approach in previous rulemakings (83 FR 41777, 84 FR 42697, and 85 FR 32460), we assume that each reviewer read approximately 50 percent of the proposed rule. We welcomed public comments on this assumption.

We have used the number of timely pieces of correspondence on the FY 2021 IPPS/LTCH proposed rule as our estimate for the number of reviewers of the proposed rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the final rule is $114.24 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 31.96 hours for the staff to review half of this final rule. For each IPPS hospital or LTCH that reviews this final rule, the estimated cost is $3,651.40 (31.96 hours × $114.24). Therefore, we estimate that the total cost of reviewing this final rule is $102,450,869 ($3,651.40 × 28,058 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a-004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of this Appendix, the net costs to the Federal Government associated with the policies finalized in this final rule are estimated at $2.293 billion.

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2021 TO FY 2022

Category	Transfers
Annualized Monetized Transfers	$2.293 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this final rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2022 relative to FY 2021 of approximately $42 million based on the data for 363 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at: *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table VI. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to the changes to the LTCH PPS. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the final payment rates and factors and other provisions presented in this final rule based on the data for the 363 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of this Appendix, the net cost to the Federal Government associated with the final policies for LTCHs in this final rule are estimated at $42 million.

TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2021 LTCH PPS TO THE FY 2022 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$42 million
From Whom to Whom	Federal Government to LTCH Medicare Providers

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business. Table VII. details the size standards for those industries that may be affected by this rule, though we expect that General Medical and Surgical Hospitals would be most affected.

TABLE VII.--SIZE STANDARDS BY AFFECTED INDUSTRY

NAICS Code	NAICS Industry Description	Size Standard
622110	General Medical and Surgical Hospitals	$ 41.5
622210	Psychiatric and Substance Abuse Hospitals	$ 41.5
622310	Specialty (except Psychiatric and Substance Abuse) Hospitals	$ 41.5

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this final rule are impacts on small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities because they do not meet the SBA definition of a small business.

HHS's practice in interpreting the RFA's reference to a ''significant economic impact on a substantial number of small entities'' is to consider effects economically ''significant'' if greater than 5 percent of small providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We believe that the provisions of this final rule relating to IPPS hospitals will have an economically significant impact on small entities as explained in this Appendix. Therefore, this RFA analysis serves as the Final Regulatory Flexibility Analysis. In ''Table I.—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2022'', we display the expected impact on the 3,198 IPPS hospitals. Column 8 indicates the total expected impact of all changes to the IPPS for various classifications of hospitals. For instance, we detail the expected impact by bed size for urban and rural hospitals. Under our final policies, we estimate that the 634 urban hospitals with a bed size of 0 to 99 would have an impact of a 2.7 percent increase in their IPPS payments, while the 311 rural hospitals with a bed size of 0 to 49 would have an impact of a 4.3 percent increase in their IPPS payments. Overall, the impact on hospitals by bed size ranges from 2.4 percent to 4.3 percent, primarily due to the hospital rate update, as discussed in section I.G. of this Appendix. We note that for some hospitals, these figures may represent the total expected impact on their inpatient hospital revenue; for other hospitals, this represents only a portion of the total expected impact, as much of their revenue comes from non-Medicare cases.

In ''Table IV. Impact of Payment Rate and Policy Changes to LTCH PPS Payments and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Payment Rate Cases for FY 2022 (Estimated FY 2022 Payments Compared to Estimated FY 2021 Payments)'' we display the expected impact on the 363 LTCH PPS hospitals. Column 8 indicates the total expected impact of all changes to the LTCH PPS for various classifications of LTCH PPS hospitals. Under our final policies, we estimate that hospitals with a bed size of 0 to 24 would have an impact of 0.6 percent, while hospitals with a bed size of 25 to 49 would have an impact of 1.0 percent. Overall, the impact on hospitals by bed size ranges from 0.6 to 1.0 percent, primarily due to the

1.9 percent annual update to the LTCH PPS standard Federal payment rate for FY 2022 and the projected 0.8 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of this Appendix.

This final rule contains a range of policies as summarized in section A. It provides descriptions of the statutory provisions that are addressed, identifies the policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. We note that section 1886(b)(3)(B) of the Act sets the requirements for the FY 2022 applicable percentage increase. Therefore, consistent with the statute, the applicable percentage increase for FY 2022 is 2.0 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements.

Under section 1886(m) of the Act, the annual update to the LTCH PPS is equal to the estimated LTCH market basket increase reduced by the productivity adjustment. Therefore, consistent with the statute, the applicable percentage increase for FY 2022 is 1.9 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 2.6 percent less the productivity adjustment of 0.7 percentage point), provided the hospital submits quality reporting data under the LTCH Quality Reporting Program. The majority of the LTCH PPS hospitals included in the impact analysis shown in ''Table IV. Impact of Payment Rate and Policy Changes to LTCH PPS Payments and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Payment Rate Cases for FY 2022 (Estimated FY 2022 Payments Compared to Estimated FY 2021 Payments)'' on average are expected to see increases in the range of 0.9 percent, primarily due to the 1.9 percent annual update to the LTCH PPS standard Federal payment rate for FY 2022 and the projected 0.8 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of this Appendix.

This final rule contains a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. The analyses discussed in this Appendix and throughout the preamble of this final rule constitutes our regulatory flexibility analysis. We solicited public comments on our estimates and analysis of the impact of our policies on small entities. We received on no public comments on those estimates and analysis.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals.

As shown in Table I. in section I.G. of this Appendix, rural IPPS hospitals with 0–49 beds (311 hospitals) and 50–99 beds (253 hospitals) are expected to experience an increase in payments from FY 2021 to FY 2022 of 4.3 percent and 2.4 percent, respectively, primarily driven by the hospital rate update, as discussed in section I.G of this Appendix. We refer readers to Table I. in section I.G. of this Appendix for additional information on the quantitative effects of the policy changes under the IPPS for operating costs.

All rural LTCHs (19 hospitals) shown in Table IV. in section I.J. of this Appendix have less than 100 beds. These hospitals are expected to experience an increase in payments from FY 2021 to FY 2022 of 1.2 percent, primarily due to the 1.9 percent annual update to the LTCH PPS standard Federal payment rate for FY 2022 and the projected 0.8 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of this Appendix.

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold level is approximately $158 million. This final rule would not mandate any requirements that meet the threshold for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this final rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act.

As discussed in section V.E.4. of the preamble of this final rule, we remain committed to working with stakeholders to determine the methodology for determining uncompensated care payments to IHS and Tribal hospitals. Consistent with Executive Order 13175, we also continue to engage in consultation with Tribal officials on this issue. We intend to use input received from these consultations with Tribal officials, as well as the comments on the proposed rule, to inform future rulemaking.

VII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2022, consistent with our approach for FY 2021, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2022

A. FY 2022 Inpatient Hospital Update

As discussed in section V.A. of the preamble to this final rule, for FY 2022, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic

health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the productivity adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

We note that, in compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we replaced the FY 2010-based IPPS operating and capital market baskets with the rebased and revised 2014-based IPPS operating and capital market baskets effective beginning in FY 2018. In this final rule, we are replacing the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022.

In the FY 2022 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we proposed to base the proposed FY 2022 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2020, which was estimated to be 2.5 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2020 forecast, we proposed a productivity adjustment of 0.2 percentage point for FY 2022. We also proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2022 market basket update and productivity adjustment for the final rule.

In the FY 2022 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2020 forecast of the 2018-based IPPS market basket and the productivity adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we presented 4 possible applicable percentage increases that could be applied to the standardized amount.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are establishing the applicable percentages increase for the FY 2022 updates based on IGI's second quarter 2021 forecast of the 2018-based IPPS market basket of 2.7 percent and the productivity adjustment of 0.7 percentage point, as discussed in section V.A. of the preamble of this final rule, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, as shown in the table in this section.

FY 2022	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.675	-0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.025	0	-2.025
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.7	-0.7	-0.7	-0.7
Applicable Percentage Increase Applied to Standardized Amount	**2.0**	**-0.025**	**1.325**	**-0.7**

B. Update for SCHs and MDHs for FY 2022

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2022 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Under current law, the MDH program is effective for discharges through September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).

As previously stated, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are establishing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs and MDHs.

C. FY 2022 Puerto Rico Hospital Update

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section V.A.1. of the preamble of this final rule.

In addition, as discussed in section V.A.2. of the preamble of this final rule, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022.

Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico

hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

Based on IGI's fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket update with historical data through third quarter 2020, in the FY 2022 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we proposed a market basket update of 2.5 percent and a productivity adjustment of 0.2 percent. Therefore, for FY 2022, depending on whether a Puerto Rico hospital is a meaningful EHR user, we stated that there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2022 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we proposed an applicable percentage increase to the FY 2022 operating standardized amount of 2.3 percent (that is, the FY 2022 estimate of the proposed market basket rate-of-increase of 2.5 percent less an adjustment of 0.2 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we proposed an applicable percentage increase to the operating standardized amount of 1.675 percent (that is, the FY 2022 estimate of the proposed market basket rate-of-increase of 2.5 percent, less an adjustment of 0.625 percentage point (the proposed market basket rate-of-increase of 2.5 percent × 0.75)/3) for failure to be a meaningful EHR user, less an adjustment of 0.2 percentage point for the productivity adjustment.

As noted previously, we proposed that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2022 market basket update and the productivity adjustment for the FY 2022 IPPS/LTCH PPS final rule.

As discussed in section V.A.1. of the preamble of this final rule, based on more recent data available for this FY 2022 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2021 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2021), we estimate that the FY 2022 market basket update used to determine the applicable percentage increase for the IPPS is 2.7 percent and a productivity adjustment of 0.7 percent. Therefore, in accordance with section 1886(b)(3)(B) of the Act, for this final rule, for Puerto Rico hospitals the more recent update of the market basket update is 2.7 percent and a productivity adjustment of 0.7 percent. For FY 2022, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we determined the following applicable percentage increases to the standardized amount for FY 2022 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, an applicable percentage increase to the FY 2022 operating standardized amount of 2.0 percent (that is, the FY 2022 estimate of the market basket rate-of-increase of 2.7 percent less an adjustment of 0.7 percentage point for the productivity adjustment)).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of 1.325 percent (that is, the FY 2022 estimate of the market basket rate-of-increase of 2.7 percent, less an adjustment of 0.675 percentage point (the market basket rate of-increase of 2.7 percent × 0.75)/3) for failure to be a meaningful EHR user, less an adjustment of 0.7 percentage point for the productivity adjustment.

D. Update for Hospitals Excluded From the IPPS for FY 2022

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this final rule, we are finalizing to use the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2022 and subsequent fiscal years. Accordingly, for FY 2022, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2022 percentage increase in the 2018-based IPPS operating market basket. For this final rule, the current estimate of the IPPS operating market basket percentage increase for FY 2022 is 2.7 percent.

E. Update for LTCHs for FY 2022

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this final rule, we are establishing an update to the LTCH PPS standard Federal payment rate for FY 2022 of 1.9 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Furthermore, in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are reducing the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are establishing an update factor of 1.019 in determining the LTCH PPS standard Federal rate for FY 2022. For LTCHs that fail to submit quality data for FY 2022, we are establishing an annual update to the LTCH PPS standard Federal rate of −0.1 percent (that is, the annual update for FY 2022 of 1.9 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a update factor of 0.999 in determining the LTCH PPS standard Federal rate for FY 2022. (We note that, as discussed in section VIII.C. of the preamble of this final rule, the update to the LTCH PPS standard Federal payment rate of 1.9 percent for FY 2022 does not reflect any budget neutrality factors).

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update of 2.0 percent. MedPAC's rationale for this update recommendation is described in more detail in this section. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 2.7 percent.

For FY 2022, consistent with policy set forth in section VIII. of the preamble of this final rule, for LTCHs that submit quality data, we are recommending an update of 1.9 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2022, we are recommending an annual update to the LTCH PPS standard Federal rate of -0.1 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2021 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by 2.0 percent with the difference between this and the update amount specified in current law to be used to increase payments under MedPAC's Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' MedPAC initially recommended in March 2019 a redesign of the current hospital quality payment programs. MedPAC stated that together, these recommendations, paired with the recommendation to eliminate the current hospital quality program incentives, would increase hospital payments by increasing the base payment rate and by increasing the average rewards hospitals receive under MedPAC's Medicare HVIP. We refer readers to the March 2021 MedPAC report, which is available for download at *www.medpac.gov*, for a complete discussion on these recommendations.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 2.0 percent, with the remainder of the applicable percentage increase specified in current law to be used to fund its recommended Medicare HVIP, section 1886(b)(3)(B) of the Act sets the requirements for the FY 2022 applicable percentage increase. Therefore, consistent with the statute, we are establishing an applicable percentage increase for FY 2022 of 2.0 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. Furthermore, we continue to appreciate MedPAC's recommendation concerning a new HVIP. We agree that continual improvement motivated by quality programs is an important incentive of the IPPS.

We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

[FR Doc. 2021–16519 Filed 8–2–21; 4:15 pm]

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FEDERAL REGISTER

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No. 154 August 13, 2021

Part III

The President

Presidential Determination No. 2021–10 of August 10, 2021—Continuation of U.S. Drug Interdiction Assistance to the Government of Colombia

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Presidential Documents

Title 3—

The President

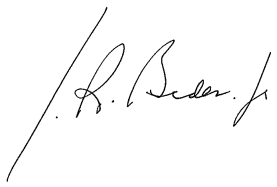
Presidential Determination No. 2021–10 of August 10, 2021

Continuation of U.S. Drug Interdiction Assistance to the Government of Colombia

Memorandum for the Secretary of State [and] the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States, and pursuant to the authority vested in me by section 1012 of the National Defense Authorization Act for Fiscal Year 1995, as amended (22 U.S.C. 2291–4), I hereby certify, with respect to Colombia, that: (1) interdiction of aircraft reasonably suspected to be primarily engaged in illicit drug trafficking in that country's airspace is necessary, because of the extraordinary threat posed by illicit drug trafficking to the national security of that country; and (2) Colombia has appropriate procedures in place to protect against innocent loss of life in the air and on the ground in connection with such interdiction, which includes effective means to identify and warn an aircraft before the use of force is directed against the aircraft.

The Secretary of State is authorized and directed to publish this determination in the *Federal Register* and to notify the Congress of this determination.



THE WHITE HOUSE,
Washington, August 10, 2021

[FR Doc. 2021–17551
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